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| Research Misconduct Policy and Procedure | Policy No.: CW-RES-001 ORA 111414-6 Version: 3.0 |
| Original Implementation Date: 03/23/2015 | Page 1 of 24 Next Review Date: 01/01/27 |
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1.0 PURPOSE / SCOPE

The purpose of this document is to establish the policies and procedures related to research misconduct by SUNY Downstate Health Sciences University (Downstate) employed faculty, staff, and students engaged in research activities (funded or unfunded) using Downstate facilities or resources, the facilities of another institution, or any other off-campus Downstate site.

Downstate is committed to excellence in all research endeavors and fosters an environment supporting research integrity and responsible conduct of research. Individuals must adhere to the highest professional standards of scientific integrity in proposing, performing, reviewing, or in reporting results, of research activities conducted under the auspices of Downstate. Downstate expects all faculty, staff, and students to report observed, suspected or apparent research misconduct in accordance with the established mechanisms for reporting such concerns and to cooperate with Downstate officials in the review of allegations and the conduct of inquiries and investigations. All parties have an obligation to provide evidence relevant to research misconduct allegations to institutional officials.

The Institutional Official (IO) has primary responsibility for research conducted under the auspices of Downstate. In doing so, the IO may delegate some responsibilities to a designee, Research Integrity Officer (RIO) and /or work in conjunction with the Office of Compliance and Audit Services (OCAS).

Downstate will thoroughly examine, in a fair and timely manner, all allegations brought forward by a complainant, acting in good faith, in which it is believed that an individual or individuals (hereafter referred to as the Respondent[s]) have committed research misconduct, in accordance with the procedures outlined in this policy. The institutional record and evidence of possible research misconduct will be handled and secured properly, in accordance with these protocols.



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2.0 POLICY

This policy establishes Downstate’s responsibilities in responding to research misconduct issues and its commitment to maintaining the integrity of our research endeavors. The guidelines provided in this policy are derived from the National Institutes of Health Intramural Research Program Policies & Procedures for Research Misconduct Proceedings and are pursuant to the Public Health Service (PHS) Policies on Research Misconduct, 42 C.F.R. Part 93 as well as guidance promulgated by the federal Office of Research Integrity (ORI). This policy will be publicly available on Downstate’s website.

3.0 DEFINITIONS

The following terms shall have the same meaning as those terms described and defined by Public Health Service Policies on Research Misconduct; 42 CFR Part 93.

- 3.1 **Accepted practices of the relevant research community:** Practices established by 42 C.F.R. 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.
- 3.2 **Allegation:** A disclosure of possible research misconduct through any means of communication (e.g., by written or oral statement) to an institutional or Health and Human Services (HHS) official.
- 3.3 **Assessment:** The consideration of whether an allegation of research misconduct appears to fall within the definition of research misconduct 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.
- 3.4 **Charge Letter:** A written notice, as well as any amendments to the notice that are sent to the respondent stating the findings of research misconduct and any administrative actions.
- 3.5 **Complainant:** A person who, in good faith, makes an allegation of research misconduct. A complainant does not necessarily have to be a member of Downstate’s workforce and may file the complaint anonymously or under a pseudonym.
- 3.6 **Compliance Officer:** The campus official responsible for compliance.
- 3.7 **Deciding Official:** The Campus President is the Deciding Official (DO). The DO makes final determinations on allegations of research misconduct and any institutional actions.



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- 3.8 **Evidence:** Any document, tangible item, or testimony offered or obtained during research misconduct proceedings 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.
- 3.9 **Fabrication:** Making up data or results and recording or reporting them.
- 3.10 **Falsification:** Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- 3.11 **Good faith:** (a) Good faith as applied to a complainant or witness means having a reasonable belief in the truth of one's allegation or testimony, based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowledge of or reckless disregard for information that would negate the allegation or testimony. (b) 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 this policy and applicable regulatory requirements. 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.
- 3.12 **Inquiry:** The process of gathering information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an Investigation.
- 3.13 **Institutional Official (IO):** The Institutional Official is responsible for handling allegations of scientific misconduct involving biomedical or behavioral research or research training. The IO is also responsible for administering the written policies and procedures for addressing allegations of research misconduct.
- 3.14 **Institutional Record:** The institutional record has three components:
- 3.14.1 Records Downstate compiled or generated during the research misconduct proceeding, except those that Downstate did not consider or rely upon. These records include, but are not limited to:
- ✓ Documentation of the Assessment, as required by §93.306(c).
 - ✓ If an Inquiry is conducted, the Inquiry report and all records (other than drafts) considered or relied upon during the Inquiry, including, but not limited to, research



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records and the transcripts of any interviews conducted during the Inquiry, information the Respondent provided to Downstate, and the documentation of any decision not to investigate as required by §93.309(c).

- ✓ If an Investigation is conducted, the Investigation report and all records (other than drafts) considered or relied upon during the Investigation, including, but not limited to, research records, the transcripts of each interview conducted pursuant to §93.310(g), and information the respondent provided to Downstate.
 - ✓ Written decision(s) by the Institutional Deciding Official under §93.314.
- 3.14.2 A single index listing all the research records and evidence that Downstate compiled during the research misconduct proceeding, except records that Downstate did not consider or rely upon.
- 3.14.3 A general description of the records that were sequestered but not considered or relied upon.
- 3.15 **Intentionally:** To act intentionally means to act with the aim of carrying out the act.
- 3.16 **Investigation:** The formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation of a finding of research misconduct, which may include a recommendation for other appropriate actions, including administrative actions.
- 3.17 **Knowingly:** To act knowingly means to act with awareness of the act.
- 3.18 **Plagiarism:** The appropriation of another person's ideas, processes, results, or words, without giving appropriate credit. (a) Plagiarism includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contributions of the author. It does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology. (b) 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.
- 3.19 **Preponderance of the Evidence:** Proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.
- 3.20 **Public Health Service (PHS):** The unit within the Department of Health and Human Services that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service,



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National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.

- 3.21 **PHS Support:** PHS funding, or applications or proposals therefore, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: funding for PHS intramural research; PHS grants, cooperative agreements, or contracts or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.
- 3.22 **Recklessly:** To act recklessly means to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism.
- 3.23 **Research:** A systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research).
- 3.24 **Research Misconduct:** The fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- Fabrication – making up data or results and recording or reporting them.
 - Falsification – manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
 - Plagiarism – the appropriation of another person’s ideas, processes, results or words without giving appropriate credit.

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

A finding of research misconduct made under this Policy requires that: (a) there be a significant departure from accepted practices of the relevant research community; and (b) the misconduct be committed intentionally, knowingly, or recklessly; and (c) the allegation be proven by a preponderance of the evidence.

- 3.25 **Research Record:** The record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, raw data, processed data, clinical research records, computer simulation software code, computer and/or statistical analysis scripts or code, images, laboratory records- both physical and electronic, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, internal reports, online content, lab meeting reports,



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journal articles and any documents and materials provided a Downstate official by a respondent in the course of the research misconduct proceeding.

- 3.26 **Respondent:** The person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.
- 3.27 **Retaliation:** Retaliation means an adverse action taken against a complainant, witness, or committee member by Downstate or one of its members in response to (a) a good faith allegation of research misconduct or (b) good faith cooperation with a research misconduct proceeding.

4.0 GENERAL PROCEDURES

4.1 Reporting Allegations of Research Misconduct: Allegations of research misconduct may be presented verbally or in writing by the complainant to the Institutional Official (IO) or to OCAS. The complainant is responsible for making allegations in good faith and maintaining confidentiality. The complainant must cooperate at all phases of the research misconduct process, including an Assessment, an Inquiry and an Investigation if required. If anonymity is requested, the IO and or OCAS will make a best effort to maintain such anonymity throughout the process, as possible.

An anonymous report may also be submitted through Downstate’s Compliance Line. Reports can be communicated via telephone at 1-877-349-SUNY (7869) or online via the “Compliance Line” link on the main Downstate web page: www.downstate.edu.

4.2 Confidentiality: Disclosure of the identity of respondents and complainants shall be limited to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding or enact corrective actions as stipulated in the findings of a proceeding.

Downstate officials involved in the proceedings will determine those who need to know, which may include public or private entities, journals, editors, publishers, and officers at other institutions. Downstate officials may manage the published research record and publicly acknowledge that certain aspects of the research record are unreliable. The IO/ designee may communicate with journals during the course of the ongoing research misconduct proceedings regarding data integrity concerns in published papers.



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This limitation on disclosure no longer applies once Downstate has made a final determination of the research misconduct findings.

4.3 Protecting Respondents, Complainants, Witnesses, and Committee Members: Downstate workforce members may not retaliate in any way against respondents, complainants, witnesses, or Inquiry/Investigation committee members. Downstate workforce members should immediately report any alleged or apparent retaliation against these parties to the IO or OCAS, who will review the matter and, where appropriate, refer the matter to applicable Downstate officials.

4.4 Ensuring Fair Assessment/Inquiry/Investigation: Downstate will take reasonable steps to ensure an impartial unbiased process to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the process.

4.5 Cooperation: All faculty, staff, and students are required to cooperate with the research misconduct proceedings, including, but not limited to, providing any information/records requested by Downstate officials and/or committee members, including specifically identifying any images, records or other raw data, making oneself available for interviews or other questioning, and responding to all requests in a timely manner. Downstate will cooperate with ORI during the proceeding, including addressing deficiencies or additional allegations if directed by ORI and assisting in administering and enforcing any HHS administrative actions imposed on Downstate workforce.

4.6 Pursuing Leads: In evaluating whether there may be additional instances of possible research misconduct relevant to the proceedings, a scoping analysis may be performed of grant applications and published papers to identify any potential additional significant issues or additional leads that should be explored at any stage of the proceedings. This includes:

- Patterns of behavior, such as the occurrence of falsifications or fabrications in multiple figures in the same paper or in multiple papers and/or grant applications over an extended period of time.
- Occurrence of the same type of fabrication or falsification in several figures, such as, but not limited to:
 - ✓ Reuse and relabeling of western blot panels, microscopy images or flow cytometry graphs; or other inappropriate reuse of the same source data.
 - ✓ Reuse of a portion or section of a western blot panel, microscopy image or other source data.
 - ✓ Reuse and relabeling with manipulation or alteration of the image or data.
- Repeated or extensive use of a methodology or technique that a Respondent used or published to generate the questioned data.



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- Testimony or other evidence that experiments were not performed, such as:
 - ✓ Respondent rarely present in the laboratory or not utilizing the laboratory instruments necessary to conduct the experiments and generate the data.
 - ✓ No laboratory notebooks or research records produced.
 - ✓ A paucity of original data on laboratory computers, hard drives, flash drives, network drives, institutionally sanctioned cloud storage, or other experimental hard drives.

4.7 Time Limitations: For PHS supported research conducted or published within six years from the date of the allegation and/or pursuant to the ‘subsequent use’ exception, any citation to, republication of, or other use of a portion of the research record (e.g. processed data, journal articles, funding proposals, data repositories) alleged to have been fabricated, falsified or plagiarized for the potential benefit of the Respondent that occurs within six years, this policy will be followed with reporting to ORI where necessary. Inclusion of the paper in a CV or bio-sketch may also trigger this subsequent use exception. For non- PHS supported research conducted or published within six years from the date of the allegation, this policy will be followed without ORI notification. Allegations on research conducted or published older than six years from the date of the allegation will be evaluated to determine whether this policy will be followed without ORI notification.

5.0 ASSESSMENT PROCEDURES

5.1 Assessment:

Upon receiving an allegation of research misconduct, the IO or designee must promptly assess the allegations, which may include an informal interview of the complainant or other witnesses, or gathering data beyond any that may have been submitted with the allegation as necessary to determine whether the allegation:

- i. Falls within the definition of research misconduct;
- ii. Is within the applicability criteria at 42 CFR §93.102, or for research outside the purview of PHS, whether the allegation falls within the time limitations imposed by this policy; and
- iii. Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

Some allegations involve multiple institutions. For such cases, the assessment period provides an opportunity to coordinate with other institutions prior to sequestration of evidence and notification to the respondent.

The IO or designee should limit the scope of the review to readily accessible information and take great care to maintain confidentiality. The IO or designee should also avoid contact with the



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respondent to help ensure the fidelity of potential evidence. The IO or designee may identify potential evidence and consider the practical arrangements needed to sequester it once the decision is made to proceed to an Inquiry.

If the IO or designee determines that the requirements for an Inquiry are not met, they must keep sufficiently detailed documentation of the Assessment to permit a later review by ORI of the reasons why an Inquiry was not conducted. This may include:

- The complainant and respondent names and position titles;
- Content of the allegations;
- Details of the research record gathered;
- PHS funding sources, proposals, research or activities; and
- Sufficiently detailed justification of the decision not to proceed to an inquiry.

The documentation of the Assessment is part of Downstate’s institutional record and will be maintained in accordance with the necessary retention time- frames.

6.0 INQUIRY PROCEDURES

6.1 Purpose of the Inquiry: Once it is determined that the criteria¹ for an Inquiry are met, the IO/Designee initiates the Inquiry process. The purpose of the Inquiry is to determine whether the allegation or apparent instance of research misconduct warrants an Investigation based on an initial review of the available evidence. The purpose of the Inquiry is not to perform a full review of the evidence or make a final determination based on the merits of the allegation.

6.2 Sequestration: Once the determination is made to convene an Inquiry, the IO/Designee will take all reasonable and practicable steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding. Research records may include forensic copies of computer hard drives or cloud storage, physical or electronic equipment, laboratory notebooks noting sample preparation and order, proprietary source files, computer simulation software code, computer and/or statistical analysis scripts or code, graphing software and files, laboratory equipment and hard drives shared between laboratories or within departments, orders and results from core facilities used to outsource experiments or data analyses, network drives and any other data that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research. Raw data may be of particularly important evidentiary value. Raw data is comprised of

¹ An Inquiry is warranted pursuant to 42 C.F.R. Part 93 if the Allegation 1) Falls within the definition of research misconduct, 2) falls within the applicability guidelines established at 93.102 and 3) is sufficiently credible and specific so that potential evidence of research misconduct may be identified).



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a researcher's primary observations that have not been processed or modified after the readings were made.

When the alleged research misconduct involves clinical research, sequestered research records may include regulatory binders, research-subject files, original source documents, case report forms sent to sponsors, human subject medical records that include research related data, communications with the funding agency, Data Safety and Monitoring Board reports, and/or Drug or Device Accountability logs.

When original records cannot be obtained, copies of records that are substantially equivalent in evidentiary value will be sequestered.

The IO/Designee and/or Office of General Counsel will work with IT to sequester all such records maintained on Downstate's network **prior** to notifying the respondent. For records that are not maintained on the network and/or are inaccessible to IT, IT personnel will sequester such records in a manner that is minimally disruptive to ongoing research. IT will attempt to sequester associated metadata of raw data files and may need to utilize specialized equipment or software. Sequestration of additional research records may will occur whenever new records become known to the IO/Designee.

A documented inventory of the sequestered records and evidence (including a description of how the sequestration was conducted) will be inventoried and secured. IT and/or Office of General Counsel will maintain the chain of custody by documenting who is responsible for the record and where they are being secured, from the moment of sequestration, throughout the proceedings, and during the required retention period. The Respondent will be provided copies or supervised access to the sequestered research records as needed.

The respondent's destruction of research records documenting the questioned research is evidence of research misconduct where a preponderance of evidence establishes that the respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations. Likewise, the respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the respondent claims to possess the records, but refuses to provide them upon request.

6.3 Timeframe: The Inquiry proceedings are generally convened within thirty (30) days of the determination to convene such Inquiry. The Inquiry, including the final report and decision of whether an Investigation is warranted, should generally be completed within ninety (90) days of the convening of the Inquiry. If/when circumstances warrant a longer period to conclude an Inquiry, Downstate will sufficiently document the reasons for exceeding the time limit in the Inquiry report. Additionally, reasonable effort will be made to notify the Respondent of any delays/ extensions to this time- frame.



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6.4 Respondent Notification of Inquiry: Within fifteen (15) business days of the determination to convene an Inquiry, the IO/Designee notifies the respondent in writing of the allegation(s). Respondent notification includes:

- The specific allegation(s);
- The rights and responsibilities of the respondent;
- The role of the Inquiry committee, IO or other designated institutional official;
- A description of the Inquiry process; and
- Copy of Downstate’s Research Misconduct Policy & Procedure.

If additional allegations are raised during the course of the proceedings, the Respondent will be notified in writing of the new allegations. If additional respondents are identified, the new Respondents will also be provided with written notification. All additional Respondents will be given the same rights and opportunities as the initial Respondent. Only allegations specific to a particular Respondent will be included in the notification to the Respondent.

6.5 Dean/Department Chair Notification of Inquiry: The Dean and Department Chair, or equivalent in the Respondent’s organizational unit, are also notified in writing by the IO/Designee of the determination to convene an Inquiry.

6.6 Composition of an Inquiry Committee: The IO or other designated institutional official will conduct a preliminary review of the evidence. The IO or other designated institutional official may choose to form an Inquiry committee, in which case the IO, in consultation with the DO, may appoint internal or external members covered under the Public Officers Law to serve on such committee. This committee may be comprised of individuals who have the professional time, resources and appropriate scientific expertise to evaluate the evidence and issues related to the allegation. In all circumstances, the Inquiry will be conducted by person(s) who meet the following criteria:

- Have appropriate scientific expertise to evaluate the evidence and issues related to the allegation; and
- Have no personal, professional, or financial conflicts of interest with the complainant or respondent.

The IO, designated institutional official, or Inquiry committee members must keep the identities of respondents, complainants and witnesses confidential and conduct the research misconduct proceedings in accordance with this policy and PHS regulations.



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6.7 Respondent Notification when Inquiry Committee is Utilized: If an Inquiry committee is utilized, the IO/Designee notifies the respondent in writing of the proposed Inquiry committee membership. The respondent will be given an opportunity to object to any proposed member based on a personal, professional, or financial conflict of interest. The respondent will submit any objections within seven days of notification of the potential committee membership. The IO makes the final determination of whether any such conflict exists.

6.8 Inquiry Process: The IO, other institutional official or Inquiry committee is responsible for determining whether the allegation or apparent instance of research misconduct warrants an Investigation based on an initial review of the available evidence. They may also identify, in the course of its duties, any issues which would justify broadening the scope of the misconduct proceeding beyond the initial allegation by pursuing any known leads. If additional Respondents are identified, a separate Inquiry for each new Respondent will not be conducted. Rather, the Inquiry will be expanded to include the new Respondents to leverage the expertise and time already expended and each Respondent will be provided with a separate Inquiry report. The Inquiry process does not result in a final determination based on the merits of the allegation and does not assess whether the alleged misconduct was intentional, knowing or reckless. In the process of fact-finding, the IO, institutional official or Inquiry committee may access evidence and documentation relating to the allegation of research misconduct and may request to interview the complainant, respondent, and/or others, if necessary and appropriate. If any interviews will be conducted, they will be transcribed. A determination of whether an Investigation is warranted is based on an initial review of the available evidence and the findings and recommendations are summarized in a written report. The Inquiry, including the final report and decision of whether an Investigation is warranted, should generally be completed within 90 days of the convening of the Inquiry. If the Inquiry report takes longer than 90 days to complete, the Inquiry record must include documentation of the reasons for exceeding the 90-day period. Reasonable effort will be made to notify the Respondent of any delays/ extensions to this time- frame.

6.9 The Draft Inquiry Report: At the conclusion of an Inquiry, a written report is prepared with the findings and recommendations. The IO, other institutional official, or Inquiry Committee charged with performing the Inquiry may rely on the assistance of the IO designee, RIO, or other lead to draft the report (and complete the final Report, below) on their behalf as long as they (the IO, other institutional official, or Inquiry Committee charged with performing the Inquiry) reviews and approves all aspects of the report. The required elements of the Inquiry report include:

- Names, professional aliases, and positions of the Respondent and complainant(s);
- If an Inquiry committee was utilized, the name of its members, including positions and subject matter expertise;
- A description of the allegation(s) of research misconduct;



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- Details about PHS funding, including any grant numbers, grant applications, contracts, and publications listing PHS support;
- Process used, i.e. Downstate’s Research Misconduct Policy and Procedure;
- Inventory of sequestered research records and other evidence reviewed and a description of how sequestration was conducted;
- Description and timeline of the analysis conducted;
- Transcripts of any interviews conducted;
- Documentation of any scientific or forensic analyses conducted;
- The basis for recommending that the allegations(s) warrant an investigation;
- The basis on which any allegations(s) do not merit further investigation;
- Documentation of potential evidence of honest error or difference of opinion;
- Any institutional actions recommended or implemented, including communications with journals or funding agencies; and any comments on the draft Inquiry report by the respondent.

6.10 Respondent’s Review of the Draft Inquiry Report: The respondent has the opportunity to review and provide written comments in response to the draft Inquiry report. The IO/Designee will forward the draft Inquiry report and attachments to the respondent. The respondent must provide any written comments within fifteen (15) days of receipt. Respondent comments will be considered and the draft report may be revised, as appropriate. Any written comments provided by the Respondent must be attached to the final Inquiry report.

The IO/Designee will transmit the final Inquiry report and any comments from Respondent to the DO, who will determine in writing whether an Investigation is warranted. The Inquiry is completed when the DO makes this determination.

6.11 DO Determination: If the Inquiry proceedings find that the allegation(s) warrant an Investigation and the DO concurs, the IO/Designee will formally convene the research misconduct Investigation.

If the Inquiry proceedings find that the allegation(s) do not warrant an Investigation and the DO concurs, the IO will maintain sufficiently detailed documentation to permit a later review by ORI of why Downstate did not proceed to an Investigation, will store these records in accordance with the retention time- frames, and will provide this documentation to ORI, upon request. If requested, the institution will make all practical, reasonable, and appropriate efforts to restore the reputation of the individual alleged to have engaged in research misconduct, but against whom no basis for allegations of research misconduct were found. Such efforts are limited to individuals and/or institutions that Downstate directly contacted in relation to the research misconduct proceedings.

6.12 Respondent Notification of Inquiry Determination: The IO/Designee notifies the Respondent in writing of the results of the Inquiry, including a copy of the final Inquiry report with all attachments.



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6.13 Dean/Department Chair Notification of Inquiry Determination: The IO/Designee will notify the Dean and Department Chair or equivalent in the Respondent's organizational unit of the results of the Inquiry.

6.14 Federal Oversight Agencies Notification of Determination to Open an Investigation: When applicable, the IO/Designee notifies ORI in writing of any decision to open an Investigation within thirty (30) days of the determination that an Investigation is warranted. This written communication includes a copy of the Inquiry report and will occur prior to the start of the Investigation.

6.15 Complainant Notification of Inquiry Determination: The IO/Designee will notify the complainant of the determination of the Inquiry when the complainant is known to the institution.

7.0 INVESTIGATION PROCEDURES

7.1 Purpose of Investigation: If Downstate determines that the criteria for an Investigation have been met, the IO/Designee will initiate the Investigation process. The purpose of the Investigation is to formally develop a factual record, pursue leads, examine the record, and recommend findings, based upon a preponderance of evidence, on each allegation and any institutional actions. As part of its investigation, Downstate will pursue diligently all significant issues and relevant leads, including any evidence of additional instances of possible research misconduct, and continue the Investigation to completion.

7.2 Timeframe: The start of an Investigation should occur within thirty (30) days after deciding an Investigation is warranted. When possible, a committee will be convened within thirty (30) days of the determination to convene an Investigation. The Investigation, including the final report and findings for each allegation, should generally be completed within one hundred eighty (180) days of the convening of the Investigation. However, if the IO/Designee determines that the Investigation will not be completed within this time- period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay. Reasonable effort will be made to notify the Respondent of any delays/ extensions to this time- frame.

7.3 Sequestration: The IO/Designee will take all reasonable or practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceedings that were not previously sequestered during the Inquiry. If original records are not available, substantially equivalent records will be sequestered. A documented inventory of the sequestered records and evidence will be updated and secured, including a description of how the sequestration was conducted. The Respondent will be provided copies or supervised access to the sequestered research records as needed. Sequestered



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materials will be maintained as part of the institutional record in accordance with the retention protocols.

As noted in Section 5.2 above, the respondent's destruction of research records documenting the questioned research is evidence of research misconduct where a preponderance of evidence establishes that the respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations. Likewise, the respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the respondent claims to possess the records, but refuses to provide them upon request.

7.4 Respondent Notification of Investigation: Within thirty (30) days of the determination to convene an investigation, IO/Designee notifies the respondent in writing of the decision to convene an investigation. Respondent notification includes:

- The specific allegation(s);
- The rights and responsibilities of the Respondent;
- The role of the investigation committee;
- The investigation process and expected timeline; and
- Copies of Downstate's Research Misconduct Policy and Procedures.

If additional allegations are raised during the course of the proceedings, the Respondent will be notified in writing of the new allegations. If additional Respondents are identified, the new Respondents will also be provided with written notification and will be added to the ongoing investigation. All additional Respondents will be given the same rights and opportunities as the initial Respondent. Only allegations specific to a particular Respondent will be included in the notification to the Respondent.

7.5 Dean/Department Chair Notification of Investigation: The Dean and Department Chair, or equivalent in the Respondent's organizational unit, are also notified in writing by the IO/Designee of the determination to convene an Investigation.

7.6 Federal Oversight Agencies Notification of the Opening on an Investigation: As stated above in §5.15, the IO/Designee notifies the appropriate federal agencies (i.e., ORI) in writing of any decision to open an Investigation within thirty (30) days of the determination that an Investigation is warranted. This written communication includes a copy of the Inquiry report and references as required by federal oversight agencies.

7.7 Appointment of the Investigation Committee: The IO/Designee, in consultation with the DO, will appoint an Investigation Committee as soon after the beginning of the Investigation as is practical. The Investigation Committee will consist of individuals who have the professional



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time, resources and appropriate scientific expertise to evaluate the evidence and issues related to the allegation. Selected individuals on the Investigation Committee cannot have any personal, professional, or financial conflicts of interest with those involved with the Investigation. Individuals appointed to the Investigation Committee may also have served on the Inquiry Committee and must be covered under the Public Officers Law.

7.8 Respondent Notification of Committee Membership: The Respondent will be notified, in writing, of the proposed Investigation Committee membership. The Respondent will be given an opportunity to object to any proposed member based on a personal, professional, or financial conflict of interest. The Respondent will submit any objections within seven (7) days of notification of the potential Committee membership. The IO/Designee makes the final determination of whether any such conflict exists.

7.9 Responsibilities of Investigation Committee: The Investigation Committee is responsible for conducting a thorough examination of all facts and evidence relevant to the Investigation to determine, based on a preponderance of evidence, whether research misconduct has occurred and, if so, to determine the responsible person and the nature and seriousness of the research misconduct. The Investigation Committee may also identify, in the course of its duties, if there are issues which would justify broadening the scope of the misconduct proceeding beyond the initial allegation and will pursue all leads. If additional Respondents are identified at this stage, a separate Inquiry and/or Investigation for each new Respondent will not be conducted. Rather, the new Respondents/ allegations will be added to the ongoing Investigation to leverage the expertise and time already expended by the Committee. Each Respondent will be provided with a separate Investigation report.

The Investigation Committee must interview the complainant, if the individual(s) is known and is available, the Respondent, and any other available persons who have been reasonably identified as having information relevant to the Investigation, including witnesses identified by the Respondent when such witnesses have information applicable to the allegations. All exhibits relevant to a particular interview will be numbered and shown to the interviewee during the interview. Interviews will be recorded and transcribed and provided to the interviewee for correction. The final transcripts will be included as exhibits in the final Investigation report. The Respondent may not be present during interviews of witnesses; however, the Respondent will be provided with copies of the transcripts appended to the report. On a case by case basis, Downstate officials may, in their sole discretion, determine it necessary to redact or anonymize portions of the transcript in a good-faith effort to protect witnesses.

The Investigation Committee comes to a finding for each allegation, determining whether research misconduct occurred, by whom and to what extent, taking into account that a finding of research misconduct requires:



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- A preponderance of evidence;
- A significant departure from accepted practices in the relevant scientific community; and
- That the research misconduct must have been committed intentionally, knowingly or recklessly. (*See definitions under §3 of this policy*).

The Investigation Committee will summarize its findings and recommendations in a written report to the DO. The IO designee, RIO or other lead for the Investigation Committee may draft the report on behalf of the Committee members and provide to the Committee for review, modification and final approval. The Investigation, including the final report and findings for each allegation, should generally be completed within 150 days of the convening of the Investigation.

7.10 Charge to the Investigation Committee: The IO/ Designee provides the charge to the Investigation Committee, which includes:

- Purpose of the Investigation;
- Definition of research misconduct;
- Requirements for findings of research misconduct;
- Obligation of confidentiality;
- Timeframe for completion;
- Identification of respondent(s);
- Specific allegation(s) to be evaluated;
- Responsibilities of the Investigation Committee, including:
 - Review of Downstate’s Research Misconduct Policy and Procedure;
 - Examination of evidence, including review of all relevant documentation;
 - Interviews of complainant, Respondent(s) and witnesses;
 - Interviews of other persons as necessary and appropriate;
 - A finding, for each allegation, determining whether research misconduct occurred, and if so, to determine the responsible person and the nature and seriousness of the research misconduct (i.e., whether it was committed intentionally, knowingly, or recklessly); and
 - Preparation of an Investigation report. As noted above, the Committee may rely on the assistance of the IO designee, RIO, or other lead to draft the report on its behalf as long as the Committee reviews and approves all aspects of the final report.

7.11 Draft Investigation Report: At the conclusion of an Investigation, the Investigation Committee prepares a written report that summarizes its findings and recommendations. The required elements of the Investigation Committee report include:

- Names of Investigation Committee members, including positions and subject matter expertise;



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- A description of the nature of the allegations of research misconduct, including any additional allegation(s) addressed during the research misconduct proceeding.
- Description and documentation of PHS support related to the alleged misconduct, including grant numbers, grant applications, contracts, and publications listing PHS support. This documentation includes known applications or proposals for support that the respondent has pending with PHS and non- PHS Federal agencies.
- 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 that contain the allegedly falsified, fabricated or plagiarized material.
- Description of the specific allegation(s) of research misconduct for consideration in the investigation of the respondent.
- Process used, i.e. Downstate's Research Misconduct Policy and Procedure.
- Inventory of the sequestered research records and other evidence reviewed (except the records the institution did not rely on), as well as a description of how any sequestration was conducted. This inventory will include manuscripts and funding proposals that were considered or relied upon during the investigation.
- Transcripts of all interviews conducted.
- Description of any scientific or forensic analyses conducted.
- A finding as to whether research misconduct occurred for each separate allegation identified during the investigation, and whether it was committed intentionally, knowingly, or recklessly.
- Identification of each finding of research misconduct as falsification, fabrication and/or plagiarism.
- Identification of any significant departure from the accepted practices of the relevant research community and that the allegation was proven by a preponderance of evidence.
- Identification of the individual responsible for each finding of research misconduct.
- Summarize the facts and analyses supporting the conclusion and consider the merits of any explanation by the Respondent.
- Identification of any publications that require correction or retraction.
- Any comments on the draft Investigation Committee report by the respondent and the Committee's consideration of those comments.
- If no finding of research misconduct is made, a detailed rationale for such conclusion will be included.

7.12 Respondent's Review of the Draft Investigation Report: The Respondent has the opportunity to review and provide written comments in response to the draft Investigation Committee report. The IO/Designee will forward the draft Investigation Committee report and attachments to the Respondent. If the Respondent requests access to evidence and documentation supporting the decision of the Investigation Committee, the Respondent may have supervised access to such evidence and documentation. The Respondent must provide any written comments within thirty (30) days of receipt of the draft Investigation Committee report. The



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Investigation Committee, after consideration of the comments of the Respondent, may revise the Investigation Committee draft report as appropriate, and prepare its final report. Transcripts from all interviews must be attached to the final Investigation Committee report. Any written comments provided by the respondent must be attached to the final Investigation Committee report. The final Investigation Committee report with all attachments is submitted to the IO/Designee.

The IO/Designee will transmit the final Investigation report and any comments from Respondent to the DO who makes the final determination.

7.13 DO Determination: If the Investigation Committee finds that research misconduct has occurred, and the DO concurs, the DO in consultation with institutional officials, will determine an appropriate course of disciplinary action in accordance with regulatory standards and established SUNY Downstate policies/procedures.

If the Investigation Committee determines that research misconduct has not occurred, and the DO concurs, then the matter is closed. If requested, the institution will make all practical, reasonable, and appropriate efforts to restore the reputation of the individual alleged to have engaged in research misconduct, but against whom no findings of research misconduct were found. Such efforts are limited to individuals and/or institutions that Downstate directly contacted in relation to the research misconduct proceedings.

7.14 Respondent Notification of Investigation Determination: The IO/Designee notifies the Respondent in writing of the final Investigation determination, including a copy of the final Investigation Committee report with all attachments.

7.15 Dean/Department Chair Notification of Investigation Determination: The Dean and Department Chair, or equivalent in the Respondent's organizational unit, are also notified in writing by the IO/Designee of the Investigation determination.

7.16 Federal Oversight Agencies Notification of the Investigation Determination: As required, the IO/Designee notifies ORI, in writing, of the Investigation Committee's findings, whether the institution accepts the Investigation Committee's findings, the final accepted institutional findings, and any completed or pending institutional actions or sanctions. This notification includes a copy of the complete institutional record.

Downstate's final determination is independent of any subsequent finding(s) from ORI. Findings from ORI are not required for Downstate to finalize its decisions regarding research misconduct or to warrant remediation, discipline, and/ or to implement other institutional actions under its relevant policies.



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7.17 Complainant Notification of the Investigation Determination: The IO/Designee will notify the complainant of the determination of the Investigation.

8.0 OTHER PROCEDURES AND SPECIAL CIRCUMSTANCES

8.1 Multiple Institutions and Multiple Respondents: If the alleged research misconduct involves multiple institutions, Downstate will work closely with the other affected institutions to determine whether a joint research misconduct proceeding should be conducted. If so, the cooperating institutions will choose a lead institution based upon factors such as where the Respondent is currently employed or where the majority of the research records are located. A written agreement may be executed to articulate how the joint proceeding will be conducted and the roles/ responsibilities of each institution.

In a joint research misconduct proceeding, the lead institution will obtain research records and other evidence pertinent to the proceeding, including witness testimony, from the other relevant institutions. By mutual agreement, the joint research misconduct proceeding may include committee members from the institutions involved. The determination of whether further inquiry and/ or investigation is warranted, whether research misconduct occurred, and the institutional actions to be taken may be made by the institutions jointly or tasked to the lead institution.

If the alleged research misconduct involves additional, new respondents, Downstate may either conduct a separate research misconduct proceeding for each new respondent or add them to the ongoing proceedings. Downstate will ensure the additional Respondent(s) receive notice of and an opportunity to respond to the allegations.

8.2 Honest Error: If a Respondent's actions were determined to be honest errors, those actions do not constitute research misconduct under this policy. The Respondent has the burden of going forward with and proving, by a preponderance of evidence, affirmative defenses raised. Downstate is not required to disprove possible honest error if no evidence of honest error exists or is introduced by the Respondent. However, if the respondent provided evidence of honest error or other evidence exists, Downstate will take into account the credibility and relevance of the evidence. The following will be considered in determining whether a Respondent's actions were honest error:

- Reviewing the data and other aspects of the Respondent's research record to ascertain whether the Respondent's practices are those established by the accepted practices of the relevant research community. The research record may include research proposals such as grant applications, raw data, processed data, computer simulation software code, computer and/or statistical analysis scripts or code, images, clinical research records, laboratory



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records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meeting reports and journal articles.

- Reviewing the research record carefully to determine whether the honest error assertion is supported by the evidence provided by the respondent.
- Evaluating whether the alleged misconduct is a single occurrence or part of a pattern by conducting a scoping analysis, including grant applications and published papers to identify any potential additional research misconduct.
- Examining the specific experiment(s) and result(s) in question to determine whether making an honest error is scientifically plausible. For instance, the Committee could assess whether the results in question were altered. If there are numerous allegations, the Committee could examine whether the majority of errors effectively changed the data to fit the hypothesis.
- Considering the Respondent's actions and behaviors in context. For example:
 - ✓ The Respondent readily admits to the mistake when responding to the allegation(s), but makes no attempt to explain how the alleged error occurred.
 - ✓ The Respondent seems to have a poor understanding of the science in question and whether researchers could easily have made the same error under the given circumstances.
 - ✓ The Respondent took reasonable steps to correct the data and/or ensure the accuracy of the questioned research.

Evidence of honest error at the Inquiry stage will be noted in the Inquiry report with sufficient detail to enable ORI's review of Downstate's reasoning for a determination to close the proceeding at the Inquiry stage.

8.3 Employment Separation: The separation of the Respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, shall not preclude or terminate the research misconduct proceeding. If the Respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the Inquiry and Investigation, as appropriate, based on the outcome of the preceding steps. If the Respondent refuses to participate in the process after resignation, the IO/Designee and any Inquiry or Investigation Committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the Respondent's failure to cooperate and its effect on the proceeding.

8.4 Respondent Admissions: Downstate will promptly notify ORI in advance if at any point during the proceedings (including the Assessment, Inquiry, or Investigation stage) it plans to close a research misconduct case because the Respondent has admitted to committing research



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misconduct or a settlement with the Respondent has been reached. If the Respondent admits to research misconduct, Downstate will not close the case until it provides ORI with the following:

- Respondent's signed, written admission which states the following:
 - ✓ The specific fabrication, falsification or plagiarism that occurred;
 - ✓ Which research records were affected (i.e., the specific published papers, manuscripts, PHS funding applications, progress reports, presentations, posters, or other research records that contain the original material that was falsified, fabricated and/or plagiarized and the compromised data);
 - ✓ A description of how the misconduct was committed, which may include image relabel and reuse, data omission, fabrication or other types of actions such as splicing, rotation or cropping;
 - ✓ Explain whether the research misconduct was conducted knowingly, intentionally, and/or recklessly; and
 - ✓ An acknowledgement that the research misconduct constitutes a significant departure from accepted practices of the relevant research community.

Admission statements may not allude to honest error, difference of opinion or mitigating factors, such as a lack of knowledge, training, instrument failure or other reasons.

- Downstate's written statement confirming the Respondent's culpability and explaining how it determined that the Respondent's admission fully addressed the scope of the misconduct.

Downstate will continue to carry the Inquiry/ Investigation through to completion and will not allow an early admission on the part of the Respondent to limit the scope of the proceedings, unless it obtains approval to do so from ORI.

8.5 Other Special Circumstances: Throughout the research misconduct proceeding, the IO/Designee will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the PHS supported research process. In the event of such a threat, the IO/Designee will, in consultation with the DO and legal counsel, take appropriate interim action to protect against any such threat. The IO/Designee must, at any time during a research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:

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



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- Federal action is required to protect the interests of those involved in the research misconduct proceeding, (or, in the case of NSF funds, of others potentially affected);
- The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

9.0 RESEARCH MISCONDUCT PROCEEDING RECORDS PROCEDURES

9.1 Institutional Record: The institutional record will contain all required elements; i.e., research records that were compiled and considered during the proceedings, assessment documentation, and inquiry/ investigation reports. Portions or the entire institutional record will be provided to ORI as follows:

- Assessment documentation will be provided upon request.
- After an Inquiry is completed, if an Investigation is warranted, ORI will be provided with a copy of the Inquiry report within 30 days of that determination. If an Investigation is not warranted, Inquiry documentation will be provided to ORI upon request. Copies of research records and other evidence reviewed will be provided to ORI upon request.
- After an Investigation is completed and the DO has made a final determination, the entire institutional record will be provided to ORI.

9.2 Retention: All documentation and records related to allegations of research misconduct, regardless of whether they resulted in an Inquiry or Investigation will be retained and secured by IO/Designee for a period of seven years after the date of the completion of the research misconduct proceedings or the completion of any HHS proceeding, whichever is later, unless custody has been transferred to HHS.

10.0 ASSURANCE PROGRAM – ANNUAL REPORTING

10.1 Annual Report on Possible Research Misconduct: On an annual basis the Downstate IO/Designee will submit an Annual Report on Possible Research Misconduct (PHS form 6349, Appendix J) to ORI (42 C.F.R. § 50.103(b)). ORI mails this form to institutions in January of each year and institutions must respond by the designated deadline, usually in March/April.

11.0 ATTACHMENTS

11.1 Research Misconduct Proceedings: Flowchart



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12.0 REFERENCES

12.1 National Institutes of Health Intramural Research Program Policies & Procedures for Research Misconduct Proceedings; Public Health Service (PHS) Policies on Research Misconduct, 42 C.F.R. Part 93.

Revision History:

| Revision | Author | Revisions Made | Effective Date |
|-----------------|---------------|------------------------------------------------------------------------------------------------------------------------|-----------------------|
| 1 | Multiple | <ul style="list-style-type: none">Modification of IO/ Designee | July 1, 2018 |
| 2 | Multiple | <ul style="list-style-type: none">Revision in alignment with revised PHS rules effective January 1, 2026 | January 1, 2026 |