Definitions for Research Misconduct Policy

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.

Adjudication. Means the formal and final decision of the Deciding Official regarding the Allegations of Research Misconduct, including the imposition of Sanctions and Corrective Actions, if any.

Administrative Action. Means an HHS action, consistent with § 93.407, taken in response to a research misconduct proceeding to protect the health and safety of the public, to promote the integrity of PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, or to conserve public funds.

Administrative Record. Means the institutional record; any information provided by the respondent to Federal ORI, including but not limited to the transcript of any virtual or in-person meetings under § 93.403(b) between the respondent and Federal ORI, and correspondence between the respondent and Federal ORI; any additional information provided to Federal ORI while the case is pending before Federal ORI; and any analysis or additional information generated or obtained by Federal ORI. Any analysis or additional information generated or obtained by Federal ORI will also be made available to the respondent.

Advanced Research. Means advanced technology development that creates new technology or demonstrates the viability of applying existing technology to new products and processes in a general way. Advanced research is most closely analogous to precompetitive technology development in the commercial sector (i.e., early phases of research and development on which commercial competitors are willing to collaborate, because the work is not so coupled to specific products and processes that the results of the work must be proprietary). It does not include development of military systems and hardware where specific requirements have been defined.

Allegation. Means a disclosure of possible Research Misconduct through any means of communication and brought directly to the attention of an institutional or HHS official, that triggers the procedures described in this policy.

Applied Research. Means original investigation that is undertaken to acquire new knowledge. It is, however, directed primarily towards a specific, practical aim or objective.

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.

Awardee institution. Means any public or private entity or organization (including a Federal, State, or local agency) that is a party to a federal agency contract, grant, cooperative agreement, or to any other transaction with a federal agency, whose purpose includes the conduct of research.

Basic Research. Means experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view. Basic research may include activities with broad or general applications in mind, such as the study of how plant genomes change, but should exclude research directed towards a specific application or requirement, such as optimizing the genome of one particular crop species.

Business Day. Means a day in which the Institution is operating and identified as being open, regardless of whether classes are in session.

Certifying Official. Means the institutional official responsible for assuring on behalf of an institution that the institution has written policies and procedures for addressing allegations of research misconduct, in compliance with 42 CFR Part 93; and complies with its own policies and procedures and the requirements of 42 CFR Part 93. The Institutional Certifying Official is responsible for certifying the content of the institution's annual report, which contains information specified by federal ORI on the institution's compliance with 42 CFR Part 93, and ensuring the report is submitted to federal ORI, as required.

Charge Letter. Means the written notice from HHS, as well as any amendments to the notice, sent to the Respondent stating the findings of Research Misconduct and any proposed HHS administrative actions.

Complainant. Means an individual who in Good Faith makes an Allegation of Research Misconduct.

Complaint. Means a set of Research Misconduct allegations. The Complaint may be by a written or oral statement or other communication. A Complaint is typically directed toward a specific Respondent and can be received at one time or sequentially.

Conflict of Interest. Means, in the context of Research Misconduct Proceedings, the actual or apparent possibility that the interests of one person may compromise or affect the interests of another person due to prior or existing personal, familial, financial, or professional relationships. Members of an Investigation or Inquiry Panel are not deemed to have a conflict of interest solely because of their role at UofL and the relationship that such a role creates with the Respondent or the Complainant (e.g., a college Dean is not deemed to have a conflict merely because the individual is the Dean of the college of a Respondent who is a faculty member).

Contract. Means an acquisition instrument awarded under the Federal Acquisition Regulation (FAR), 48 CFR chapter 1.

Corrective Action or Sanction. Means any action determined to be necessary to address Research Misconduct or Questionable Research Practices. For example, Corrective Actions or Sanctions could include retraction of published manuscripts, return of funded grants to the agency, withdrawal of submitted grant applications, withdrawal of manuscripts submitted for publication, withdrawal of abstracts submitted for presentation at meetings, additional conditions on awards, requiring third-party certification of accuracy or compliance with particular policies, regulations, guidelines, or special terms and conditions; limitations on certain activities or expenditures under an active award or special reviews of requests for funding, government-wide suspension or debarment or other actions.

Day. Means calendar day, unless otherwise specified. If the last day of a designated time period falls on a weekend or a day on which the university is closed, the period will expire at the close of business on the next business day. In regard to transactions with federal ORI, if a deadline falls on a Saturday, Sunday, or Federal holiday, the deadline will be extended to the next day that is not a Saturday, Sunday, or Federal holiday.

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 Executive Vice President, Research and Innovation, at the University of Louisville is the Deciding Official, barring any conflict.

Departmental Appeals Board (DAB). Means the organization, within the HHS Office of the Secretary, established to conduct hearings and provide impartial review of disputed decisions made by HHS operating components.

Difference of opinion. Difference of opinion means an alternative view held by a researcher who is substantively engaged in the scientific subject area. It generally contrasts with a prevailing opinion included in a published research record or generally accepted by the relevant scientific community. The differing opinion must concern scientific data, methodology, analysis, interpretations, or conclusions, not policy opinions or decisions unrelated to data practices.

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.

Experimental Development. Means systematic work, drawing on knowledge gained from research and practical experience and producing additional knowledge, which is directed to creating new products or processes or to improving existing ones. Experimental Development includes producing materials, devices, and systems or methods, including the designing, constructing and testing experimental prototypes.

Fabrication. Means making up data or results and recording or reporting them.

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.

Federal Office of Research Integrity or federal ORI. Means the office established by Public Health Service Act section 493 (42 U.S.C. 289b) and to which the HHS Secretary has delegated responsibility for addressing Research Integrity and Misconduct issues related to PHS- supported activities.

Funding component. Means any organizational unit of the PHS authorized to award grants, contracts, or cooperative agreements for any activity covered by this part involving research or research training; funding components may be agencies, bureaus, centers, institutes, divisions, offices, or other awarding units within the PHS.

Good Faith. Means, as applied to a Complainant or witness, 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 it Knowingly or Recklessly disregards information that would negate the Allegation or testimony. Good Faith as applied to an Inquiry or Investigation Panel 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 42CFR Part 93. 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.

HHS or Secretary. Means the United States Department of Health and Human Services, the Secretary of HHS or any other official or employee of HHS to whom the Secretary delegates authority.

Home Institution. Means the Institution with jurisdiction over a specific Allegation because it is the Institution where the Research Misconduct took place, and retains and/or is responsible for the retention of the original Research Records.

Honest Error. Means an accidental or inadvertent mistake made in Good Faith while using a normal degree of care and attention. Honest Error is an exception to the definition of Research Misconduct or an affirmative defense to an Allegation of Research Misconduct in which a Respondent asserts that the questioned conduct resulted from an unintended error rather than Intentional, Knowing, or Reckless distortion of the Research Record. The Respondent carries the burden of establishing that Honest Error (or other affirmative defense such as Difference of Opinion) more likely than not explains the Fabrication, Falsification, or Plagiarism.

Inquiry. Means the preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures outlined in UofL RES 1.04a.

Institution. Means any person or entity that applies for or receives PHS support for any activity or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities

related to that research or training. This includes, but is not limited to, colleges and universities, PHS intramural biomedical or behavioral research laboratories, research and development centers, national user facilities, industrial laboratories or other research institutes, research institutions, and independent researchers. For the purposes of RES 1.04, Institution shall mean the University of Louisville or one of its statutory affiliated corporations.

Institutional Member(s). Means an individual (or individuals) who is employed by, is an agent of, or is affiliated by contract or agreement with the University of Louisville or one of its statutory affiliated corporations. Institutional members may include, but are not limited to, attorneys, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, technicians, postdoctoral and other fellows, students, volunteers, subject matter experts, consultants, visiting scholars, visiting students, agents and contractors, subcontractors, and sub awardees and their employees.

Institutional Official. Means person with direct authority over faculty and staff appointments, salaries, promotions, signatory authority, or division of institutional resources, such as the assignment of graduate students or other trainees, progress or promotion of students, funding or space for faculty who are conducting research. Term includes anyone holding administrator positions, even temporarily. Term includes, but is not limited to individuals serving as: Deans, Associate Deans, and Assistant Deans; Institute and Center Directors; University Counsel; University Compliance Officers; Director of Audit Services; Provost, Vice Provosts, Associate Vice Provosts, and Assistant Vice Provosts; President, Executive Vice Presidents, Senior Vice Presidents, Vice Presidents, Associate Vice Presidents, and Assistant Vice Presidents; Department Heads; Directors of Sponsored Programs, Technology Transfer, Research Integrity, Human Subjects Protection; and chairs of the Institutional Review Board, Institutional Biosafety Committee, Institutional Animal Care and Use Committee, Conflict Review Board, and other similar committees created in the future.

Institutional Record. Means the (a) records that the institution compiled during the Research Misconduct Proceeding, except to the extent the institution subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained. These records include, but are not limited to: (1) The assessment report; (2) If an inquiry is conducted, the inquiry report and all records (other than drafts of the report) in support of that report, including, but not limited to, research records and the transcripts of any interviews conducted during the inquiry, information the respondent provided to the institution, and the documentation of any decision not to investigate; (3) If an investigation is conducted, the investigation report and all records (other than drafts of the report) in support of that report, including, but not limited to, research records, the transcripts of each interview conducted, and information the respondent provided to the institution; and (4) Decision(s) by the Deciding Official, such as the written decision from the Deciding Official with the final determination of Research Misconduct findings (whether the institution found Research Misconduct, and if so, who committed the misconduct) and implemented institutional actions; (b) A single index listing all the Research Records and Evidence that the Institution compiled during the Research Misconduct Proceeding, except records the Institution did not consider or rely on.; and (c) A general description of the records that were sequestered but not considered or relied on.

Intentionally. Means to act with the aim of adding Falsification, Fabrication, or Plagiarism into the Research Record.

Interference. Means intentional, unauthorized taking, sequestering, or materially damaging any research-related apparatus, reagents, biological materials, writings, data, hardware, software, or any other substance or device used or produced in the conduct of research. See also **Research Vandalism.**

Interim Actions. Means any actions of the university taken prior to Adjudication to comply with laws or regulations, or for one or more of the following reasons:

1. to protect the public, research community, research subjects, or patients, including their health and safety;
2. to protect the interests of students, faculty, or staff;

3. to preserve Evidence;
4. to protect the university, state, or federal resources or interests, including contractual obligations; or,
5. to protect the interests of those involved in the Research Misconduct Proceedings.

Investigation. Means the formal development of a factual record and the examination of that record that meets the criteria and follows the procedures of RES 1.04a.

Investigation Panel. Means a group of at least three Institutional Members charged with conducting the Investigation. Members of the Standing Inquiry Panel are eligible to serve on the Investigation Panel.

Knowingly. Means to act with awareness that Falsification, Fabrication, or Plagiarism is being committed.

NASA research. Means research wholly or partially funded or supported by NASA involving an awardee institution or a NASA installation. This definition includes research wholly or partially funded by NASA appropriated funds, or research involving the use of NASA facilities, equipment, or personnel.

NASA research discipline. Means one of the following areas of research that together comprise NASA's research mission for aeronautics, space science, Earth science, biomedicine, biology, engineering and physical sciences (physics and chemistry).

Notice. Means a written or electronic communication served in person or sent by mail or its equivalent to the last known street address, facsimile number, or email address of the addressee.

NSF. Means the National Science Foundation

Public Health Service (PHS). Means the following components within HHS: the Office of the Assistant Secretary for Health, the Office of Global Affairs, the Administration for Strategic Preparedness and Response, the Advanced Research Projects Agency for Health, the Agency for Healthcare Research and Quality, the Agency for Toxic Substances and Disease Registry, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the Substance Abuse and Mental Health Services Administration, and any other components of HHS designated or established as components of the Public Health Service.

PHS Regulation. Means the Public Health Service regulation establishing standards for institutional investigations into allegations of scientific misconduct, which is set forth at 42 C.F.R. Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science."

PHS Support. Means PHS funding, or applications or proposals for PHS funding, 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; subawards, contracts, or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements, or contracts.

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.

Preponderance of 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.

Questionable Research Practices. Means practices that do not constitute Research Misconduct but that violate applicable laws, regulations, or other governmental requirements, or University rules or policies, of which the Respondent had received notice or of which the Respondent reasonably should have been aware, for proposing, performing, reviewing, or reporting Research.

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

Research and Development. Research means a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. This definition encompasses basic and applied research, including research training activities not included in formal instruction and all development activities. Development is the systematic use of knowledge and understanding gained from research, directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes. For purposes of this policy, both Research and Development apply.

Research Integrity. Research integrity refers to the use of honest and verifiable methods in proposing, performing, and evaluating research; reporting research results and maintaining the research record with particular attention to adherence to rules, regulations, and guidelines; and following accepted practices of the relevant research community.

Research Integrity Officer (RIO). Means the institutional official responsible for administering the Institution's written policies and procedures for addressing Allegations of Research Misconduct in compliance with 42 CFR Part 93. The Director of the ORI is the RIO for the University of Louisville.

Research Integrity Panel (RIP). Means nine to eleven Institutional Members, selected for disciplinary breadth in consultation with the Council of Research Deans and Council of Academic Officers. The RIP's charge is to conduct the Inquiry and Investigation in a Research Misconduct Proceeding. Members of the RIP are guided by RES 1.04 and RES 1.04a.

Research Misconduct. Means Fabrication, Falsification, or Plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research Misconduct does not include honest errors or differences of opinion.

Research Misconduct Proceeding. Means any actions and associated records related to alleged Research Misconduct defined in RES 1.04, including but not limited to, allegation assessments, inquiries, investigations, federal ORI oversight reviews, hearings and administrative appeals.

Research Record. Means any data or results, in any media or format, which embodies the facts resulting from research. Data or results may be in physical or electronic form. A Research Record includes, but is not limited to, , grant or contract applications, whether funded or unfunded; grant or contract progress and other reports, raw data, processed data, clinical research records, notes, correspondence, videos, audio recordings, photographs, X-ray film, slides, biological materials, computer files and printouts, manuscripts and publications, equipment use logs, laboratory procurement records, animal facility records, human and animal subject protocols, medical charts, patient research files, computer code, musical scores, musical composition, choreography, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meeting reports, and journal articles.

Research Vandalism. Means is intentionally causing material harm to the research or scholarly work of others, and may include stealing, damaging or destroying the property of others, such as research papers, supplies, equipment, or products of research or scholarship; disrupting active experiments; or altering or deleting products of research, including data.

Respondent. Means the individual against whom an Allegation of Research Misconduct is directed or who is the subject of a Research Misconduct Proceeding.

Responsible Conduct of Research (RCR). Means the conduct of Research in an honest and professional manner while maintaining rigorous adherence to professional standards. RCR means planning, performing, reporting, and reviewing Research in accordance with objectivity, honesty, openness, accountability, fairness, and stewardship.

Retaliation. Means an adverse action taken against a Complainant, Witness, or panel member by an Institution or one of its members in response to: a Good Faith Allegation of Research Misconduct; or Good Faith cooperation with a Research Misconduct Proceeding.

Sequestration. Means the collection and segregation of research records, equipment, and other tangible or intangible information for the specific purpose of assessing Allegations as part of the Research Misconduct investigative process. ORI has the authority and responsibility for the Sequestration of Research Records relative to Research Misconduct Allegations at UofL. All appropriate rights are accorded to the Respondent in the act of sequestering Research Records, as outlined in the Roles and Responsibilities of the Respondent Matrix for this policy.

Sponsored Programs. Means research, training, and instructional projects involving funds, materials, gifts, or other compensation from external governmental or non-governmental organizations under agreements with UofL.

Statutory Affiliates. University of Louisville Research Foundation, University of Louisville Athletic Association and any other affiliates added in the future.

Suspension and Debarment Official (SDO). Means the HHS official authorized to impose suspension and debarment, which are the actions that Federal agencies take to disqualify persons deemed not presently responsible from doing business with the Federal Government.

ULORI. Means the Office for Research Integrity, the office within the University of Louisville responsible for overseeing Research Misconduct Proceedings and promoting the Responsible Conduct of Research at the University of Louisville.