

Additional Definitions for APS 920808, *Misconduct in Academic Research and Scholarship*

§ 93.200 **Accepted practices of the relevant research community.** - 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.

§ 93.201 **Administrative action** - 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.

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

§ 93.203 **Allegation** - 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.

§ 93.204 **Assessment** - 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.

§ 93.205 **Charge letter** - Charge letter means the written notice, as well as any amendments to the notice, sent to the respondent stating the findings of research misconduct and any proposed HHS administrative actions.

§ 93.206 **Complainant** - Complainant means an individual who in good faith makes an allegation of research misconduct.

§ 93.207 **Contract** - Contract means an acquisition instrument awarded under the Federal Acquisition Regulation (FAR), 48 CFR chapter 1.

§ 93.208 **Day** - Day means calendar day unless otherwise specified. 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.

§ 93.209 **Departmental Appeals Board or DAB** - Departmental Appeals Board or 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.

§ 93.210 **Evidence** - 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.

§ 93.211 **Fabrication** - Fabrication means making up data or results and recording or reporting them.

§ 93.212 **Falsification** - 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.

§ 93.213 **Funding component** - 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.

§ 93.214 **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 part. 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.

§ 93.215 **Inquiry** - Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of § 93.307 through § 93.309.

§ 93.216 **Institution** - Institution means any person 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.

§ 93.217 **Institutional Certifying Official** - Institutional 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 this part; and complies with its own policies and procedures and the requirements of this part. The Institutional Certifying Official is responsible for certifying the content of the institution's annual report, which contains information specified by ORI on the institution's compliance with this part, and ensuring the report is submitted to ORI, as required.

§ 93.218 **Institutional Deciding Official** - 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.

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

§ 93.220 **Institutional record** - The institutional record comprises:

(a) The records that the institution compiled or generated during the research misconduct proceeding, except records the institution did not consider or rely on. These records include, but are not limited to:

(1) Documentation of the assessment as required by § 93.306(c).

(2) If an inquiry is conducted, the inquiry report and all records (other than drafts of the report) considered or relied on during the inquiry, including, but not limited to, research records and the transcripts of any transcribed interviews conducted during the inquiry, information the respondent provided to the institution, and the documentation of any decision not to investigate as required by § 93.309(c).

(3) If an investigation is conducted, the investigation report and all records (other than drafts of the report) considered or relied on during the investigation, including, but not limited to, research records, the transcripts of each interview conducted pursuant to § 93.310(g), and information the respondent provided to the institution.

(4) Decision(s) by the Institutional Deciding Official, such as the written decision from the Institutional Deciding Official under § 93.314.

(5) The complete record of any institutional appeal consistent with § 93.315.

(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.

(c) A general description of the records that were sequestered but not considered or relied on.

§ 93.221 **Intentionally** - To act intentionally means to act with the aim of carrying out the act.

§ 93.222 **Investigation**-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.

§ 93.223 **Knowingly** - To act knowingly means to act with awareness of the act.

§ 93.224 **Notice** - 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.

§ 93.225 **Office of Research Integrity or ORI** - Office of Research Integrity or 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.

§ 93.226 **Person** - Person means any individual, corporation, partnership, institution, association, unit of government, or other legal entity, however organized.

§ 93.227 **Plagiarism** - Plagiarism means 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.

§ 93.228 **Preponderance of the evidence** - 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.

§ 93.229 **Public Health Service or PHS** - Public Health Service or PHS consists of 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.

§ 93.230 **PHS support** - 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.

§ 93.231 **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.

§ 93.232 **Research** - 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) by establishing, discovering, developing, elucidating, or confirming information or underlying mechanisms related to biological causes, functions, or effects; diseases; treatments; or related matters to be studied.

§ 93.233 **Research Integrity Officer or RIO** - Research Integrity Officer or RIO refers to the institutional official responsible for administering the institution's written policies and procedures for addressing allegations of research misconduct in compliance with this part.

§ 93.234 **Research misconduct** - 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 differences of opinion.

§ 93.235 **Research misconduct proceeding** - Research misconduct proceeding means any actions related to alleged research misconduct taken under this part, including allegation assessments, inquiries, investigations, ORI oversight reviews, and appeals under subpart E of this part.

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

§ 93.237 **Respondent** - Respondent means the individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

§ 93.238 **Retaliation** - Retaliation means an adverse action taken against a complainant, witness, or committee member by an institution 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.

§ 93.239 **Secretary or HHS** - Secretary or HHS means the Secretary of HHS or any other official or employee of HHS to whom the Secretary delegates authority.

§ 93.240 **Small institution** - Small institution means an institution that may be too small to conduct an inquiry or investigation into an allegation of research misconduct as required by this part without actual or apparent conflicts of interest.

§ 93.241 **Suspension and Debarment Official or SDO** - 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.