

**TITLE 310. OKLAHOMA STATE  
CHAPTER 10. HUMAN SUBJECTS PROTECTION [NEW]**

**RULEMAKING ACTION:**

PERMANENT final adoption

**PROPOSED RULES:**

Chapter 10. Human Subjects Protection [NEW]

**AUTHORITY**

Oklahoma State Board of Health; 63 O.S. 1991, §§ 1-104 & 1-106

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**Legislative approval:**

**Final adoption:**

**Effective:**

**SUPERSEDED EMERGENCY ACTIONS:**

"n/a"

**INCORPORATION BY REFERENCE:**

**Incorporated standards:**

This chapter hereby incorporates by reference Part 46 of Title 45 of the Code of Federal Regulations (45 C.F.R. Part 46) and Part 50, Subpart A of Title 42 of the Code of Federal Regulations (42 C.F.R. Part 50) as if fully set forth herein.

**Incorporating rules:**

310:10-1-2 and 310:10-1-4

**Availability:**

The incorporated standards are available for viewing from Shari Kinney, R.N., M.S. Institutional Review Board Administrator, Room 709, Oklahoma State Department of Health, 1000 NE 10<sup>th</sup> Street, Oklahoma City, Oklahoma 73117-1299.

**ANALYSIS:**

The proposal defines the responsibility of the Oklahoma State Department of Health to provide an organizational structure in accordance with 45 C.F.R. Part 46 to establish and maintain an environment dedicated to the ethical principles for safeguarding the rights and welfare of the human beings recruited to participate in research activities. The policy describes the responsibilities of the OSDH and the OSDH Institutional Review Board, and outlines responsibilities for the Department with regard to research misconduct.

**CONTACT PERSON:**

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**PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTION 308.1(A), WITH AN EFFECTIVE DATE OF:**

**SUBCHAPTER 1. GENERAL PROVISIONS**

**310:10-1-1. General purpose**

The Oklahoma State Department of Health is committed to providing an organizational structure in accordance with Title 45 of the Code of Federal Regulations Part 46 (45 C.F.R. Part 46) in order to establish and maintain an environment dedicated to the ethical principles for safeguarding the rights and welfare of the human beings recruited to participate in research activities. The OSDH Institutional Review Board (IRB) has been established to comply with federal regulations to protect the rights and welfare of human research participants. The OSDH IRB has the responsibility to assure that the risks of proposed research are justified by the potential benefits to the participants and to society, and that risks are minimized to the extent possible consistent with sound research design. The OSDH IRB must assure that the risks of research do not fall disproportionately on one group while the potential benefits accrue to another. The OSDH IRB oversees the consent process to assure voluntary and knowing consent to participate in research. Individuals who are particularly vulnerable or whose capacity to consent may be in doubt require additional protection during the consent process. The OSDH IRB must assure that the research is designed to respect individual privacy and preserve the confidentiality of private information. The OSDH IRB has the on-going oversight responsibility of approved research to monitor the welfare of the participants and to determine that the risks and potential benefits remain unchanged. The OSDH IRB may approve, disapprove, or require modifications to research protocols. It may also suspend or terminate its approval of ongoing (previously approved) research.

**310:10-1-2. Scope**

This Chapter applies to all individuals at the OSDH engaged in research involving human subjects. The Commissioner of Health retains final authority to determine whether a particular activity is subject to this policy. This Chapter applies to any person paid by, under the control of, or affiliated with the OSDH, such as scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at OSDH. Research activities are exempt from this policy if they are determined by the OSDH IRB to meet criteria established in 45

C.F.R. § 46.101, which is incorporated by reference in this Chapter.

**310:10-1-3. Definitions**

The following words and terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Allegation" means any written or oral statement or other indication of possible scientific misconduct made to an institutional official.

"Board" means the Board of Health.

"Commissioner" means the Commissioner of Health.

"Conflict of interest" means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

"Deciding official" means the institutional official appointed by the Commissioner of Health who makes final determinations on allegations of scientific misconduct and any responsive institutional actions.

"Good faith allegation" means an allegation made with the honest belief that scientific misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

"Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or through identifiable private information of an individual.

"IRB" means the OSDH Institutional Review Board established in accord with 45 C.F.R. Part 46 for the purposes expressed in this Chapter.

"IRB approval" means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

"Inquiry" means gathering information and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation[42 C.F.R. § 50.102].

"Institution" means the Oklahoma State Department of Health unless the context clearly indicates otherwise.

"Investigation" means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct[42 C.F.R. § 50.102].

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily

life or during the performance of routine physical or psychological examinations or tests.

"OHRP" means the Office of Human Research Protections within the U.S. Department of Health and Human Services (DHHS) that is responsible for compliance and oversight relative to the DHHS regulations for the protection of human subjects.

"ORI" means the Office of Research Integrity within the DHHS that is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service.

"OSDH" means the Oklahoma State Department of Health.

"PHS" means the U.S. Public Health Service, an operating component of the DHHS.

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

"PHS support" means PHS grants, contracts, or cooperative agreements or applications therefore.

"Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this Chapter, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

"Research Integrity Officer" means the OSDH official appointed by the Commissioner of Health responsible for assessing allegations of scientific misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.

"Research record" means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

"Respondent" means the person against whom an allegation of scientific misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There may be more than one respondent in any inquiry or investigation.

"Retaliation" means any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has in good faith, made an allegation of scientific misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation. Action taken may include an intentional act of omission.

"Scientific misconduct or misconduct in science" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data [42 C.F.R. § 50.102.]

"Whistleblower" means a person who makes an allegation of scientific misconduct.

#### **310:10-1-4. Incorporations by reference**

(a) This Chapter hereby incorporates by reference Part 46 of Title 45 of the Code of Federal Regulations (45 C.F.R. Part 46) as if fully set forth herein.

(b) This Chapter hereby incorporates by reference Part 50, Subpart A of Title 42 of the Code of Federal Regulations (42 C.F.R. Part 50) as if fully set forth herein.

### **SUBCHAPTER 3. FEDERALWIDE ASSURANCE OF PROTECTION FOR HUMAN SUBJECTS**

#### **310:10-3-1. Adherence to ethical principles**

All of the Oklahoma State Department of Health's human subject activities, and all human subject activities of the OSDH Institutional Review Boards designated under the OSDH Federalwide Assurance, regardless of funding source, will be guided by the ethical principles in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

#### **310:10-3-2. Conditions of federalwide assurance**

- (a) The conditions of the federalwide assurance apply whenever:
- (1) the OSDH IRB provides review and oversight of federally-supported human subject research, regardless of where the research takes place or by whom it is conducted;
  - or
  - (2) the OSDH becomes engaged in federally-supported human subject research.
- (b) The OSDH becomes so engaged whenever:
- (1) OSDH employees or agents intervene or interact with living individuals for purposes of federally-supported research;

(2) OSDH employees or agents obtain, release, or access individually identifiable private information for purposes of federally-supported research; or

(3) The OSDH receives a direct federal award to conduct human subject research, directly or where all activities involving human subjects are carried out by a subcontractor or collaborator.

**310:10-3-3. Compliance with 45 C.F.R. Part 46**

Federally-supported human subject research for which the OSDH IRB provides review and oversight will comply with 45 C.F.R. Part 45. All human subject research supported by the Department of Health and Human Services (HHS) will comply with all Subparts of HHS regulations at Title 45 Code of Federal Regulations Part 46 (45 C.F.R. Part 46.) All federally-supported human subject research will also comply with any additional human subject regulations and policies of the supporting federal or state department or agency. All federally-supported human subject research will comply with any human subject regulations and policies of any relevant regulatory federal or state department or agency.

**310:10-3-4. Authority of IRB**

Except for research exempted or waived under 45 C.F.R. § 46.101(b)&(i), all human subject research will be reviewed, prospectively approved, and subject to continuing oversight by the OSDH IRB. The OSDH IRB will have authority to approve, require modifications in, or disapprove the covered human subject research.

**310:10-3-5. Informed consent**

Except where specifically waived or altered by the OSDH IRB under 45 C.F.R. §§ 46.101(i), 46.116(c)&(d), or 46.117(c) all human subject research will require written informed consent, in nonexculpatory language understandable to the subject (or subject's legally authorized representative), including the following basic elements per 45 C.F.R. § 46.116(a)&(b):

- (1) Identification as research; purposes, duration, and procedures; procedures which are experimental;
- (2) Reasonable foreseeable risks or discomforts;
- (3) Reasonable expected benefits to the subject or others;
- (4) Alternative procedures or treatments, if any, that might be advantageous to the subject;
- (5) Extent of confidentiality to be maintained;
- (6) Whether compensation or medical treatment are available if injury occurs (if more than minimal risk);
- (7) Whom to contact for answers to questions about the research, subjects' rights, and research-related injury;
- (8) Participation is voluntary; refusal to participate, or discontinuation of participation, will involve no penalty or loss of benefits to which subject is entitled; and

(9) When appropriate, additional elements per 45 C.F.R. § 45.116.

**310:10-3-6. IRB procedures**

The OSDH and the OSDH IRB have established (or will establish within 90 days of the effective date of this Chapter), and will provide to Office of Human Research Protections upon request, written procedures for:

(1) verifying whether proposed activities qualify for exemption from, or waiver of, IRB review;

(2) conducting IRB initial and continuing review, approving research, and reporting IRB findings to the investigator and the institution;

(3) determining which projects require review more often than annually, and which projects need verification from sources other than the investigator that no material changes have occurred;

(4) ensuring that changes in approved research are reported promptly and are not initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to the subject; and

(5) ensuring prompt reporting to the IRB, institutional officials, the relevant department or agency head, any applicable regulatory body, and OHRP of any:

(A) unanticipated problems involving risks to subjects or others in any covered research;

(B) serious or continuing noncompliance with federal, institutional, or IRB requirements; and

(C) suspension or termination of IRB approval for federally-supported research.

**310:10-3-7. Assurance training**

The OSDH Signatory Official, the OSDH Human Protections Administrator, and the OSDH IRB Chairperson will personally complete the relevant OHRP basic educational modules, or comparable training approved by OHRP, prior to submitting the Assurance. Members and staff of the IRB will complete relevant training before reviewing human subject research. Research investigators must complete appropriate institutional training before conducting human subject research.

**310:10-3-8. Investigator training**

The OSDH and the OSDH IRB have established (or will establish within 90 days of the effective date of this Chapter), and will provide to OHRP upon request, education and oversight mechanisms (appropriate to the nature and volume of its research) to verify that research investigators, IRB members and staff, and other relevant personnel maintain continuing knowledge of, and comply with, relevant federal regulations, OHRP guidance, other applicable guidance, state and local law, and institutional policies for the protection of human subjects. The OSDH and the

OSDH IRB will require documentation of such training from research investigators as a condition for conduction human subject research.

**310:10-3-9. Compliance and knowledge of local context**

The OSDH is responsible for verifying that the OSDH IRB designated under the Federalwide Assurance agree to comply with Sections 310:10-3-1 through Sections 310:10-3-8 and that the OSDH IRB possess appropriate knowledge of the local context in which research for which the OSDH IRB is responsible will be conducted.

**310:10-3-10. Assurance of protection for human subjects**

The OSDH is responsible for ensuring that all institutions and investigators collaborating in its federally-supported human subject research operate under an appropriate Assurance of Protection for Human Subjects. All institutions engaged in such research, including subcontractors and subgrantees, must hold their own Assurance.

**310:10-3-11. Institutional support of the IRB**

The institution will provide the OSDH IRB with resources, professional staff, and support staff sufficient to carry out their responsibilities efficiently and effectively.

**310:10-3-12. Unaffiliated investigation**

The activities of individual research investigators who are not employees or agents of the institution may be covered under the Assurance only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and OSDH IRB oversight. Institutions must maintain such commitment agreements on file and provide copies to OHRP upon request.

**310:10-3-13. Update of federalwide assurance**

Information provided under the Federalwide Assurance will be updated every 36 months, even if no changes have occurred, in order to maintain an active Assurance.

**SUBCHAPTER 5. COMPLIANCE WITH THE REGISTRATION OF THE OKLAHOMA STATE DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD**

**310:10-5-1. FDA regulated research**

The OSDH IRB will only review FDA-Regulated Research that has already been approved by an Institutional Review Board that complies with FDA regulations.

**310:10-5-2. Ethical principles**

All IRB activities related to human subject research should be guided by the ethical principles in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the



Protection of Human Subjects of Biomedical and Behavioral Research.

**310:10-5-3. Compliance with 45 C.F.R. Part 46**

Federally-supported human subject research for which the OSDH IRB provides review and oversight will comply with 45 C.F.R. Part 45. All human subject research supported by the Department of Health and Human Services (HHS) will comply with all Subparts of HHS regulations at Title 45 Code of Federal Regulations Part 46 (45 C.F.R. Part 46). All federally-supported human subject research will also comply with any additional human subject regulations and policies of the supporting federal or state department or agency. All federally-supported human subject research will comply with any human subject regulations and policies of any relevant regulatory federal or state department or agency.

**310:10-5-4. Authority of the OSDH IRB**

Except for research exempted or waived under 45 C.F.R. § 46.101(b)&(i), all research for which the IRB is responsible will be reviewed, prospectively approved, and subject to continuing oversight by the IRB. The IRB has the authority to approve, require modifications in, or disapprove the research for which it is responsible.

**310:10-5-5. Informed consent**

Except where specifically waived or altered by the IRB under 45 C.F.R. § 46.101(i), 46.116(c)&(d), or 46.117(c) of all research for which the IRB is responsible requires written informed consent, in nonexculpatory language understandable to the subject (or the subject's legally authorized representative), including the following basic elements per 45 C.F.R. § 46.116(a)&(b):

- (1) Identification as research; purposes, duration, and procedures; procedures which are experimental;
- (2) Reasonable foreseeable risks or discomforts;
- (3) Reasonably expected benefits to the subject or others;
- (4) Alternative procedures or treatments, if any, that might be advantageous to the subject;
- (5) Extent of confidentiality to be maintained;
- (6) Whether compensation or medical treatment are available if injury occurs (if more than minimal risk);
- (7) Whom to contact for answers to questions about the research, subjects' rights, and research-related injury;
- (8) Participation is voluntary; refusal to participate, or discontinuation of participation, will involve no penalty or loss of benefits to which subject is entitled; and
- (9) When appropriate, additional elements per 45 C.F.R. § 46.116(b).

**310:10-5-6. IRB procedures**

The IRB will establish written procedures for:

(1) conducting IRB initial and continuing review, approving research, and reporting IRB findings to the investigator and the institution;

(2) determining which projects require review more often than annually, and which projects need verification from sources other than the investigator that no material changes have occurred;

(3) ensuring that changes in approved research are reported promptly and are not initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to the subject; and

(4) ensuring prompt reporting to the IRB, institutional officials, the relevant department or agency head, any applicable regulatory body, and OHRP of any:

(A) unanticipated problems involving risks to subjects or others in any covered research;

(B) serious or continuing noncompliance with federal, institutional, or IRB requirements; and

(C) suspension or termination of IRB approval for federally-supported research.

**310:10-5-7. Compliance and knowledge of local context**

The IRB will ensure that it has appropriate knowledge of the local context in which research for which it is responsible will be conducted.

**310:10-5-8. IRB Training**

The IRB Chairperson, IRB members, IRB staff, and human subject research investigators will complete appropriate education related to the protection of human subjects before reviewing or conducting human subject research.

**310:10-5-9. Provision of investigator training**

The IRB will ensure the existence of adequate education and oversight mechanisms (appropriate to the nature and volume of the research being conducted) to verify that research investigators, IRB members and staff, and other relevant personnel maintain continuing knowledge of, and comply with, relevant Federal regulations, OHRP guidance, other applicable guidance, state and local law, and IRB determinations and policies for the protection of human subjects. The IRB will require documentation of such training from research investigators as a condition for conducting human subject research.

**310:10-5-10. Institutional support of the IRB**

The IRB will endeavor to ensure that it is provided with resources, professional staff, and support staff appropriate to the nature and volume of the research for which it is responsible.

**310:10-5-11. Update of IRB Registration**

The OSDH IRB will update the IRB Registration at least every 36 months in order to maintain active registration. Failure to update this information may result in termination of the IRB's registration with HHS.

**310:10-5-12. IRB membership requirements**

45 C.F.R. § 46.107 specifies IRB membership requirements as follows:

(1) The IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the entity. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(2) Every effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

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

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

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

(6) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of

issues, which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

## **SUBCHAPTER 7. RESEARCH INTEGRITY**

### **310:10-7-1. Responsibility for research integrity**

The responsibility under 45 C.F.R. Part 46 includes authority to suspend or terminate IRB approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's actions and shall be reported promptly to the investigator, appropriate OSDH officials, and the Commissioner of Health.

### **310:10-7-2. Usage**

This Chapter establishes procedure that will be followed when an allegation of possible misconduct in science is received by an OSDH official. Particular circumstances in an individual case may dictate variation from this procedure deemed in the best interests of OSDH and PHS. Any change from these procedures also must ensure fair treatment to the subject of the inquiry or investigation. The Commissioner of Health should approve any significant variation in advance.

### **310:10-7-3. Research Integrity Officer**

(a) The Commissioner will appoint the Research Integrity Officer (RIO) who will have primary responsibility for implementation of these procedures. The RIO Officer will be an employee of OSDH who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

(b) The RIO will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The RIO will do everything possible to ensure that confidentiality is maintained.

(c) The RIO will assist inquiry and investigation committees and all employees in complying with these procedures and with applicable standards imposed by government or external funding sources. The RIO shall maintain files of all documents and evidence and shall maintain the confidentiality and the security of the files.

(d) The RIO reports to ORI shall keep ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential DHHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of federal funds and otherwise protect the

public interest.

**310:10-7-4. Whistleblower**

- (a) The whistleblower will have the opportunity to:
- (1) Testify before the inquiry and investigation committees;
  - (2) Review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony;
  - (3) Be informed of the results of the inquiry and investigation;
  - (4) Be protected from retaliation.
- (b) If the RIO has determined that the whistleblower may be able to provide pertinent information on any portions of the draft report, these portions will be given to the whistleblower for comment.
- (c) The whistleblower is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation.

**310:10-7-5. Respondent**

- (a) The respondent will:
- (1) Be informed of the allegations when an inquiry is opened;
  - (2) Be notified in writing of the final determinations and resulting actions;
  - (3) Be interviewed by and present evidence to the inquiry and investigation committees;
  - (4) Review the draft inquiry and investigation reports;
  - (5) Have the right to advice of counsel.
- (b) The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is not found to have engaged in scientific misconduct, he or she has the right to receive assistance from OSDH in restoring his or her reputation.

**310:10-7-6. Deciding official**

The Deciding Official will be appointed by the Commissioner and will receive the inquiry and/or investigation report and any written comments made by the respondent or the whistleblower on the draft report. The Deciding Official will consult with the RIO or other appropriate officials and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions.

**310:10-7-7. Responsibility to report misconduct**

All employees or individuals associated with OSDH should report observed, suspected, or apparent misconduct in science to the RIO. If an individual is unsure whether a suspected incident falls within the definition of scientific misconduct, he or she may call the RIO to discuss the suspected misconduct informally.

If the circumstances described by the individual do not meet the definition of scientific misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem. At any time, an employee may have confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer and will be counseled about appropriate procedures for reporting allegations.

**310:10-7-8. Protecting the whistleblower**

(a) The RIO will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations.

(b) The RIO will ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status at the institution and will review instances of alleged retaliation for appropriate action. A grievance may be filed by the RIO for the whistleblower or the whistleblower may file for him or herself.

(c) Employees should immediately report any alleged or apparent retaliation RIO.

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

**310:10-7-9. Protecting the respondent**

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

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

**310:10-7-10. Cooperation with inquiries and investigations**

OSDH employees will cooperate with the RIO and other OSDH officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the RIO or other OSDH officials on misconduct allegations.

### **310:10-7-11. Preliminary assessment of allegations**

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

### **310:10-7-12. Conducting the inquiry**

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

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

#### **(c) Appointment of the inquiry committee.**

(1) The RIO, in consultation with other OSDH officials as appropriate, will appoint an inquiry committee and committee chair within 10 days of the initiation of the inquiry. The inquiry committee shall consist of individuals who:

(A) Do not have real or apparent conflicts of interest in the case;

(B) Are unbiased; and

(C) Have the necessary expertise to evaluate the evidence and issues related to the allegation.

(D) May be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside the institution.

(2) The Inquiry Committee will interview the principals and key witnesses, and conduct the inquiry.

(3) The RIO shall notify the respondent of the proposed committee membership in 10 days.

(4) If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within 5 days, the RIO shall

determine whether to replace the challenged member or expert with a qualified substitute.

**(d) Charge to the committee and the first meeting.**

(1) The RIO will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation as required by the PHS regulation.

The purpose is not to determine whether scientific misconduct definitely occurred or who was responsible.

(2) At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The RIO and institutional counsel will be present or available throughout the inquiry to advise the committee as needed.

**(e) Inquiry process.** The inquiry committee will interview the whistleblower, the respondent, and key witnesses as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the RIO and OSDH counsel, the committee members will decide whether there is sufficient evidence of possible scientific misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

**310:10-7-13. The inquiry report**

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

**(b) Comments on the draft report by the respondent and the whistleblower.** After first redacting the identity of the whistleblower, the RIO will provide the respondent with a copy of the redacted draft inquiry report for comment and rebuttal, and will provide the whistleblower, if he or she is identifiable, with portions of the draft inquiry report that address the whistleblower's role and opinions in the investigation.



(c) **Confidentiality.** The RIO shall establish reasonable conditions for review to protect the confidentiality of the draft report.

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

**310:10-7-14. Inquiry decision, notification, and confidentiality**

(a) **Decision by deciding official.** The RIO will transmit the final report and any comments to the Deciding Official, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible scientific misconduct to justify conducting an investigation. The inquiry is completed when the Deciding Official makes this determination, which will be made within 60 days of the first meeting of the inquiry committee. Any extension of this period will be based on good cause and recorded in the inquiry file.

(b) **Notification.** The RIO will notify both the respondent and the whistleblower in writing of the Deciding Official's decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The RIO will also notify all appropriate institutional officials of the Deciding Official's decision.

(c) **Confidentiality.** A decision recommending further investigation pursuant to subsection (a) above shall be deemed to be confidential pursuant to 51 O.S. § 24A.12 and shall not be publicly disseminated beyond the persons identified in subsection (b) above.

**310:10-7-15. Time limit for completing the inquiry report**

The inquiry committee will normally complete the inquiry and submit its report in writing to the RIO no more than 60 calendar days following its first meeting, unless the RIO approves an extension for good cause. If the RIO approves an extension, the reason for the extension will be entered into the records of the case and the report. The respondent also will be notified of the extension.

**310:10-7-16. Conducting the investigation**

(a) **Purpose of the investigation.** The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly

important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

**(b) Sequestration of the research records.** The Research Integrity Officer will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. This sequestration should occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

**(c) Appointment of the Investigation Committee.** The Research Integrity Officer, in consultation with other OSDH officials as appropriate, will appoint an investigation committee and the committee chair within 10 days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. Individuals appointed to the investigation committee may also have served on the inquiry committee. The Research Integrity Officer will notify the respondent of the proposed committee membership within 5 days. If the respondent submits a written objection to any appointed member of the investigation committee or expert, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

**(d) Charge to the committee and the first meeting.**

**(1) Charge to the committee.** The Research Integrity Officer will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, defines scientific misconduct, and identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness. During the

investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the Research Integrity Officer, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

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

(e) **Investigation process.** The investigation committee will be appointed and the process initiated within 30 days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation. The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the committee should interview the whistleblower(s), the respondents(s), and other individuals who might have information regarding aspects of the allegations. Interviews of the respondent should be tape recorded or transcribed. All other interviews should be transcribed, tape recorded, or summarized. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

### **310:10-7-17. The investigation report**

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

(b) **Comments on the draft report.**

(1) **Respondent.** After first redacting the identity of the whistleblower, the Research Integrity Officer will provide the respondent with a copy of the redacted draft investigation report for comment and rebuttal. The respondent will be allowed 5 days to review and comment on

the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence.

(2) **Whistleblower.** The Research Integrity Officer will provide the whistleblower, if he or she is identifiable, with those portions of the draft investigation report that address the whistleblower's role and opinions in the investigation. The report should be modified, as appropriate, based on the whistleblower's comments.

(3) **Institutional counsel.** The draft investigation report will be transmitted to the institutional counsel for a review of its legal sufficiency. Comments should be incorporated into the report as appropriate.

(4) **Confidentiality.** In distributing the draft report, or portions thereof, to the respondent and whistleblower, the Research Integrity Officer will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the Research Integrity Officer may request the recipient to sign a confidentiality statement or to come to his or her office to review the report. The identity of the whistleblower will be subject to public disclosure only as the RIO may determine is reasonable and appropriate by balancing the needs of the whistleblower to remain confidential with the needs of the institutional review board to comply with federal regulations enacted to protect the rights and welfare of human research participants.

(c) **Institutional review and decision.** Based on a preponderance of the evidence, the Deciding Official will make the final determination whether to accept the investigation report, its findings, and the recommended institutional actions. If this determination varies from that of the investigation committee, the Deciding Official will explain in detail the basis for rendering a decision different from that of the investigation committee in the institution's letter transmitting the report to ORI. The Deciding Official's explanation should be consistent with the PHS definition of scientific misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The Deciding Official may also return the report to the investigation committee with a request for further fact-finding or analysis. The Deciding Official's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review. When a final decision on the case has been reached, the Research Integrity Officer will notify both the respondent and the whistleblower in writing. In addition, the Deciding Official will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which

falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

(d) **Transmittal of the final investigation report to ORI.** After comments have been received and the necessary changes have been made to the draft report, the investigation committee should transmit the final report with attachments, including the respondent's and whistleblower's comments, to the Deciding Official, through the Research Integrity Officer.

(e) **Time limit for completing the investigation report.** An investigation should ordinarily be completed within 120 days of its initiation, with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the Deciding Official for approval, and submitting the report to the ORI.

### **310:10-7-18. Requirements for reporting to ORI**

(a) An institution's decision to initiate an investigation must be reported in writing to the Director, ORI, on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of scientific misconduct, and the PHS applications or grant number(s) involved. ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report. Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.

(b) If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.

(c) If the institution determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Research Integrity Officer will file periodic progress reports as requested by the ORI.

(d) When PHS funding or applications for funding are involved and an admission of scientific misconduct is made, the Research Integrity Officer will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to

sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, the institution cannot accept an admission of scientific misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

(e) The Research Integrity Officer will notify ORI at any stage of the inquiry or investigation if:

- (1) there is an immediate health hazard involved;
- (2) there is an immediate need to protect Federal funds or equipment;
- (3) there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
- (4) it is probable that the alleged incident is going to be reported publicly; or
- (5) the allegation involves a public health sensitive issue, e.g., a clinical trial; or
- (6) there is a reasonable indication of possible criminal violation. In this instance, the institution must inform ORI within 24 hours of obtaining that information.

### **310:10-7-19. Institutional administrative actions**

(a) OSDH will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated. If the Deciding Official determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the Research Integrity Officer. The actions may include:

- (1) withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific misconduct was found.
- (2) removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
- (3) restitution of funds as appropriate.

(b) **Termination of OSDH employment or resignation prior to completing inquiry or investigation.** The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible scientific misconduct has been reported, will not preclude or terminate the misconduct procedures. If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation will proceed. If the respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the

allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

(c) **Restoration of the respondent's reputation.** If the institution finds no misconduct and ORI concurs, after consulting with the respondent, the Research Integrity Officer will undertake reasonable efforts to restore the respondent's reputation if necessary. Depending on the particular circumstances, the Research Integrity Officer should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of scientific misconduct was previously publicized, or expunging all reference to the scientific misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Deciding Official.

(d) **Protection of the whistleblower and others.** Regardless of whether the institution or ORI determines that scientific misconduct occurred, the Research Integrity Officer will undertake reasonable efforts to protect whistleblowers who made allegations of scientific misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the Deciding Official will determine, after consulting with the whistleblower, what steps, if any, are needed to restore the position or reputation of the whistleblower. The Research Integrity Officer is responsible for implementing any steps the Deciding Official approves. The Research Integrity Officer will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the whistleblower.

(e) **Allegations not made in good faith.** If relevant, the Deciding Official will determine whether the whistleblower's allegations of scientific misconduct were made in good faith. If an allegation was not made in good faith, the Deciding Official will determine whether any administrative action should be taken against the whistleblower.

(f) **Interim administrative actions.** Institutional officials will take interim administrative actions, as appropriate, to protect Federal funds and ensure that the purposes of the Federal financial assistance are carried out.

### **310:10-7-20. Record retention**

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer or committees. The Research Integrity Officer will maintain and dispose of the records of any inquiry or investigation in compliance with the approved records retention schedule for the office of the Commissioner of Health. The ORI or other authorized DHHS personnel will be given access to the

records upon request. These records are subject to public review or copying unless otherwise exempt from disclosure pursuant to the Oklahoma Open Records Act.



