TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 2. PROCEDURES OF THE OKLAHOMA STATE DEPARTMENT OF HEALTH

RULEMAKING ACTION

Notice of proposed PERMANENT rulemaking.

PROPOSED RULES:

Subchapter 1. Description of Organization
310:2-1-1 Purpose [AMENDED]
310:2-1-2 Definitions [REVOKED]
310:2-1-3 Organization [AMENDED]
Subchapter 3. General operations and Procedures
310:2-3-1 Address
310:2-3-2 Office hours [REVOKED]
310: 2-3-5 Access to agency records pursuant to the Open Records Act [AMENDED]
Subchapter 7. Additional Procedures for Administrative Penalty Proceedings
Part 1. Environmental Health Penalties
310:2-7-1 Applicability [AMENDED]
310: 2-7-4 Administrative Compliance Order [AMENDED]
Subchapter 15. Application Forms
310:2-15-1 Required description of forms [AMENDED]
310:2-15-3 Uniform Employment Application for Nurse Aide Staff [AMENDED]
Subchapter 17. Local Public Health Enhancement Grants
310:2-17-1 Purpose [REVOKED]
310:2-17-2 Definitions [REVOKED]
310:2-17-3 Contingency [REVOKED]
310:2-17-4 Eligibility for grant program [REVOKED]
310:2-17-5 Grant description [REVOKED]
310:2-17-6 Grant program announcements [AMENDED]
310:2-17-7 Grant program guidelines [REVOKED]
310:2-17-8 Grant limitations [REVOKED]
310:2-17-9 Application evaluation process [REVOKED]
310:2-17-10 Approval of grants [REVOKED]
310:2-17-11 Grant program administrations [REVOKED]
Subchapter 19. Procedures for Determining Agency Cost Allocation to the Construction Industries Board
310:2-19-1 Purpose and authority [REVOKED]
310:2-19-2 Definitions [REVOKED]
310:2-19-3 Procedures and methods [REVOKED]
310:2-19-4 Dissemination of the adjusted and indirect cost agreements [REVOKED]
Subchapter 31. Human Subjects Protection
310:2-31-1 General purpose [AMENDED]
310:2-31-2 Scope [AMENDED]
310:2-31-3 Definitions [REVOKED]
310:2-31-6 Authority of IRB [AMENDED]
310:2-31-7 IRB procedures [AMENDED]
310:2-31-8 Training [AMENDED]
310:2-31-9 Compliance and knowledge of local context [REVOKED]
310:2-31-11 FDA regulated research [REVOKED]
310:2-31-12 Usage of procedures for allegation of possible misconduct in science [AMENDED]
310:2-31-13 Research Integrity Officer (RIO) [AMENDED]

310:2-31-14 Whistleblower [AMENDED]
310:2-31-15 Respondent [AMENDED]
310:2-31-16 Deciding official [AMENDED]
310:2-31-17 Responsibility to report misconduct [AMENDED]
310:2-31-18 Protecting the whistleblower [AMENDED]
310:2-31-19 Protecting the respondent [AMENDED]
310:2-31-22 Conducting the inquiry [AMENDED]
310:2-31-23 The inquiry report [AMENDED]
310:2-31-24 Inquiry decision, notification, and confidentiality [AMENDED]
310:2-31-26 Conducting the investigation [AMENDED]
310:2-31-27 The investigation report [AMENDED]
310:2-31-28 Requirements for reporting to ORI [AMENDED]
310:2-31-29 Institutional administrative actions [AMENDED]
310:2-31-30 Record retention [AMENDED]

SUMMARY:

This Chapter implements the procedures of the State Department of Health. Repeal of the designated Sections is in response to the Governor's Executive Order 2020-03 to streamline language through a word sweep to remove unnecessary or duplicative language. Repeal of certain Sections is necessary to align the rules with existing statutes and other administrative rules.

Section 310:2-1-1 establishes the purpose of the Subchapter and contained unnecessary language. Section 310:2-1-2 consists of definitions and contained unnecessary language. Section 310:2-1-3 on the organization of the Department and contained unnecessary language.

Section 310:2-3-1 deletes the Department's old address and adds the new address.

Section 310:2-3-2 listed the Department's office hours which are not necessary in promulgated rules.

Section 310:2-3-5 refers to the Oklahoma Open Records Act and has been better phrased to align with that Act.

Section 310:2-7-1 governs individual proceedings and required amending to comply with other rules.

Section 310:2-7-4 implements Administrative Compliance Orders, requires amending to comply with other rules, and allows Commissioner designee to issue administrative compliance orders.

Section 310:2-15-1 updated a legal citation.

Section 310:2-15-3 applies to Uniform Employment Application for Nurse Aide Staff. It was amended to repeal language which repeated statutory language.

Subchapter 17 encompasses Local Public Health Enhancement Grants and was revoked because there is no requirement to promulgate rules in this area and this provision could be included in internal policies rather than in promulgated rules.

Subchapter 19 governs Procedures for Determining Agency Cost Allocation to the Construction Industries Board. It was revoked because the Department no longer oversees this Board.

Subchapter 31 details the authority and procedures of the Oklahoma State Department of Health Institutional Review Board and the procedures for allegation of possible misconduct in research. The proposed changes are in response to the Governor's Executive Order 2020-03. Changes have been made to reduce the length and improve clarity but will not impact the current implementation of these rules.

AUTHORITY:

Commissioner of Health, 63 O.S. § 1-104; Construction Industries Board, 59 O.S. §§ 1000.1-1000.9

COMMENT PERIOD:

January 15, 2021 through the close of the Department's normal business hours, 5 PM, on February 16, 2021. Interested persons may informally discuss the proposed rules with the contact person identified below; or may, through the close of the Department's normal business hours, 5 PM, on February 16, 2021, submit written comment to the contact person identified below, or may, at the hearing, ask to present written or oral views.

PUBLIC HEARING:

Pursuant to 75 O.S. § 303(A), the public hearing for the proposed rulemaking in this chapter

shall be on February 16, 2021, via WebEx accessible from the site https://oklahoma.gov/health/organization/public-hearings.html, from 9AM to noon. The meeting may adjourn earlier if all attendees who signed up to comment have completed giving their comments. The alternate date and time in the event of extreme inclement weather or technical difficulties disrupting or preventing the meeting is February 23, 2021, via WebEx accessible from the site https://oklahoma.gov/health/organization/public-hearings.html, from 9AM to noon. Those wishing to present oral comments should be registered to speak by 9:15 a.m. Directions for comment registration will be provided on the website. The hearing will close at the conclusion of comments from those registered to speak. Interested persons may attend for the purpose of orally submitting data, views, or concerns about the rule proposal described and summarized in this Notice.

REQUESTS FOR COMMENTS FROM BUSINESS ENTITIES:

Business entities affected by these proposed rules are requested to provide the agency with information, in dollar amounts if possible, on the increase in the level of direct costs such as fees, and indirect costs such as reporting, recordkeeping, equipment, construction, labor, professional services, revenue loss, or other costs expected to be incurred by a particular entity due to compliance with the proposed rule. Business entities may submit this information in writing through the close of the Department's normal business hours, 5 PM, on February 16, 2021, to the contact person identified below.

COPIES OF PROPOSED RULES:

The proposed rules may be obtained for review from the contact person identified below or via the agency website at www.ok.gov/health.

RULE IMPACT STATEMENT:

Pursuant to 75 O.S., § 303(D), a rule impact statement is available through the contact person identified below or via the agency website at www.ok.gov/health.

CONTACT PERSON:

Audrey C. Talley, Agency Rule Liaison, Oklahoma State Department of Health, 123 Robert S. Kerr Avenue, Oklahoma City, OK 73102, phone (405) 426-8563, e-mail AudreyT@health.ok.gov.

INITIAL RULE IMPACT STATEMENT

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 2. PROCEDURES OF THE STATE DEPARTMENT OF HEALTH

1. DESCRIPTION:

This Chapter sets forth procedures of the State Department of Health.

Section 2-1-1 establishes the purpose of the Subchapter and contains unnecessary language. Section 2-1-2 consists of definitions and contains unnecessary language. Section 2-1-3 speaks to the organization of the Department and contains unnecessary language. Section 2-3-1 replaces the Department's old address with the new address. Section 2-3-2 lists the Department's office hours which are not necessary to be in promulgated rules. Section 2-3-5 refers to the Oklahoma Open Records Act and can be better phrased to align with that Act.

Section 2-7-1 governs individual proceedings and requires amending to comply with other rules. Section 2-7-4 implements Administrative Compliance Orders, requires amending to comply with other rules, and allows Commissioner designee to issue administrative compliance orders.

Section 2-15-3 applies to Uniform Employment Application for Nurse Aide Staff. It is amended to repeal language that repeats statutory language.

Subchapter 17 is being revoked. It encompasses Local Public Health Enhancement Grants. There is no requirement to promulgate rules in this area and this provision could be included in internal policies rather than in promulgated rules.

Subchapter 19 is being revoked. It governs Procedures for Determining Agency Cost Allocation to the Construction Industries Board. Due to a statutory change, the Department no longer oversees this Board and this Subchapter is to be repealed.

Subchapter 31. Human Subjects Protection: The purpose of the proposed amendment is to comply with the Governor's Executive Order 2020-03. Changes reduce the length of the document, remove duplicative language and improve clarity but do not change operational procedures or how the rule is implemented.

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:

No person will be affected by these changes in Subchapters 1 through 19 as the Subchapters either contain unnecessary language, are duplicative of statutory law or are being repealed to comply with existing statutory or administrative law. There is no cost impact.

Persons affected by the proposed amendment to Subchapter 31 include internal and external researchers who review or are engaged in conducting research by, for or with the Oklahoma State Department of Health. The proposed amendment will not increase or decrease costs for any affected persons.

3. DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:

There is no substantive change by the repeal of the Subchapters. The repeal complies with the Governor's Executive Order 2020-03 to streamline rules.

As the proposed amendment does not result in any changes to the implementations or operations by the OSDH IRB, there is no direct benefit for affected persons.

4. ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:

There is no economic impact, cost of compliance or fee changes related to the proposed amendment.

5. COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:

There are no costs associated with implementation.

6. IMPACT ON POLITICAL SUBDIVISIONS:

There will be no impact on political subdivisions and it will not require their cooperation in implementing or enforcing the proposed amendment.

7. ADVERSE EFFECT ON SMALL BUSINESS:

There is no known adverse economic effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act.

8. EFFORTS TO MINIMIZE COSTS OF RULE:

There are no less costly means currently identified.

9. EFFECT ON PUBLIC HEALTH AND SAFETY:

No effect on public health is expected as a result of this rule change.

10. DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:

There will be no detrimental effects on public health and safety by amendments to this rule.

11. PREPARATION AND MODIFICATION DATES:

This rule impact statement was prepared on December 1, 2020.

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 2. PROCEDURES OF THE STATE DEPARTMENT OF HEALTH

SUBCHAPTER 1. DESCRIPTION OF ORGANIZATION

310:2-1-1. Purpose

~~(a)~~ These rules implement the Administrative Procedures Act, 75 O.S. ~~1991, Section~~ § 250 et seq., as amended ("APA"). These rules govern formal proceedings of the Department and may be supplemented by procedural rules within a particular departmental area. Informal proceedings may be held as announced by the Department or as agreed with any person.

~~(b) These rules are adopted to simplify procedure, avoid delays, save expenses, and facilitate the administration of the Public Health Code of Oklahoma and other laws assigned to the Oklahoma State Department of Health for administration. To that end, the provisions of these rules shall be given a fair and impartial construction.~~

310:2-1-2. Definitions

~~Unless the context otherwise requires, singular words shall be deemed to include the plural, and masculine words to include the feminine, and vice versa.~~ The following words or terms, when used in this Chapter, shall have the following meaning unless the context clearly indicates otherwise:

"Administrative Law Judge" means a person appointed by the Commissioner of Health to conduct an individual hearing under the Administrative Procedures Act and may be ~~a~~ an employee or a private attorney with whom the Department has a contract for services.

"Board" means the Oklahoma State Board of Health.

"Commissioner of Health" and **"Commissioner"** mean the Oklahoma State Commissioner of Health, the chief executive officer of the Department. References in this Chapter to the Commissioner may include a designee of the Commissioner of Health. Designations shall be subject to such powers and limitations as are specified in writing.

"Department" means the Oklahoma State Department of Health.

"Respondent" means the person(s) or legal entity(ies) named in a petition for an individual proceeding, against whom relief is sought.

310:2-1-3. Organization

The Department shall be organized and divided into such departmental areas and divisions as the ~~Board~~ Commissioner deems desirable for efficiency. Such organization and division may be revised by the ~~Board~~ Commissioner as ~~it finds~~ necessary or expedient. ~~Copies of the organizational chart are available upon request to the Office of the Commissioner.~~

SUBCHAPTER 3. GENERAL OPERATIONS AND PROCEDURES

310:2-3-1. Address

The principal office of the Department is ~~Suite 305,~~ Oklahoma State Department of Health, ~~1000 N.E. 10th Street, Oklahoma City, Oklahoma 73117-1299~~ 123 Robert S. Kerr Avenue, Oklahoma City, Oklahoma 73102.

310:2-3-2. Office hours [REVOKED]

~~Office hours are from 8:00 a.m. to 4:30 p.m., unless otherwise designated by the Commissioner, each day except Saturday and Sunday and legal holidays established by statute or by the Governor.~~

310:2-3-5. Access to agency records pursuant to the Open Records Act

(a) **Official records.** Official records include records required to be maintained by law, the record in individual proceedings, records submitted to the agency by any person and any other "record" as that term is defined by the Oklahoma Open Records Act, 51 O.S. § 24A.1, et seq.,(OORA).

(b) **Access to official records.** ~~Every record defined by subparagraph (a) above wherein disclosure is not otherwise specifically excepted by law or the OORA is~~ Records available to the public pursuant to the Oklahoma Open Records Act, 51 O.S. § 24A.1 et seq., are subject to inspection and mechanical reproduction under the provisions set forth below.

(c) **Initial procedural requirements.** A request for inspection shall ~~may~~ be submitted electronically or in writing. To encourage a fully articulated and accurate response to a request, the request shall be submitted on a form made available by OSDH ~~recommends a request be submitted via its online form~~, online and ~~that~~ the requester must reasonably describe the records sought. Additionally, if applicable, every request must specify a time period for which records are being sought. A request submitted in the manner above, reasonably describing the records sought and stating an appropriate time period for the records being sought will be timely acknowledged and further processed for a review and inspection. ~~If, consistent~~ Consistent with the OORA, agency personnel may determine that the requester is required to pay, in advance, any fees due pursuant to subparagraph (h) below.

(d) **Requests received.** Requests submitted to the agency will not be deemed to have been received unless and until the request has been identified by agency personnel as a request properly submitted in accordance with these rules. After a determination is made of the estimated ~~any~~ fees to gather the records requested, the agency will ~~remit an advice of the cost to~~ advise the requester of the cost. Upon receipt of the requested search fee, the request will be deemed to have been received by the agency and will then be timely processed for inspection.

(e) **Abandonment.** Any request not confirmed by a tender of the requisite search fee within thirty (30) days of advice by the agency shall be deemed to be abandoned, unless, within the time stated, the requester can show cause why the confirmation should be delayed or postponed.

(f) **Cooperation with the agency.** If the requester fails to furnish additional information reasonably necessary to identify the records sought or otherwise enable agency personnel to accurately process the request, the processing of the subject request may be suspended by agency personnel. A request that remains suspended for a period exceeding ~~(~~thirty (30) days shall be deemed abandoned.

(g) ~~**Appeal**~~ **Unavailable or confidential records.** If the agency cannot comply with the request for disclosure, the requester shall be notified of the adverse determination, stating the reason(s) therefor.

(h) **Fees.** The following are fees for preparing records for production:

(1) Paper Records - The fees for preparing paper records are those set forth in the OORA.
~~(A) Regular Copy - $0.25 per page~~
~~(B) Certified Copy - $1.00 per page~~

(2) Electronic Records - If request is for records to be produced in a format other than an electronically transmitted digital file, the preferred digital media to the agency, ~~The~~ the agency will recoup the actual cost of transferring the records to the requester's media.

(3) Other Fees - ~~$30.00 per hour~~ The hourly fee for requests that are solely for commercial purpose or that cause excessive disruption of the ~~agencies~~ agency's essential functions is in accordance with the schedule filed at the Oklahoma County Clerk's office. 'Excessive disruption' fees apply to requests that require more than eight (8) hours of actual employee work time to compile.

(4) Actual cost charged to OSDH by any third party related to obtaining records.

SUBCHAPTER 7. ADDITIONAL PROCEDURES FOR ADMINISTRATIVE PENALTY PROCEEDINGS

PART 1. ENVIRONMENTAL HEALTH PENALTIES

310:2-7-1. Applicability

The requirements of Part 1 of this Subchapter, Environmental Health Penalties, are in addition to ~~the preceding~~ other requirements of this Chapter governing individual proceedings and are applicable to matters~~,~~ where the Department is a party~~,~~ brought under 63 O.S.~~, 1991 Sections~~ §1-1701.1A.

310:2-7-4. Administrative Compliance Order

(a) **When issued.** Fifteen (15) days or more after service of any required Notice of Violation (NOV) upon the Respondent, or such reduced period as the Petitioner believes necessary to render the order reasonably effectual, the Commissioner of Health or ~~Deputy Commissioner~~ his or her designee may issue an Administrative Compliance Order requiring compliance and specifying penalties for noncompliance. The entry of an Administrative Compliance Order initiates an individual proceeding under this Subchapter and shall meet the requirements of a petition as stated above.

(b) **Must specify.** The Administrative Compliance Order shall specify the facts and conclusions upon which it is based and shall set a time for the Respondent to comply with the applicable regulations. The Administrative Compliance Order shall specify the penalty, not to exceed the statutory maximum per day of non-compliance, to be assessed in the event that the Respondent fails to comply with the Order within the prescribed time.

(c) **Service.** The Administrative Compliance Order shall be served in accordance with ~~Subchapter 5~~ OAR 310:2-21-4. The Order shall advise the Respondent that it shall become final unless a hearing is requested within fifteen (15) days of service of the Order. If a hearing is requested, proceedings shall promptly commence.

(d) **Hearing.** Based on the hearing, the Administrative Compliance Order will be sustained, modified, or dismissed. If the hearing process extends beyond any compliance deadline specified in the Administrative Compliance Order, fines specified in the Order for violations of the Order will continue to accrue during the hearing process unless the Hearing Officer stays the penalty upon request for good cause shown.

SUBCHAPTER 15. APPLICATION FORMS

310:2-15-1. Required descriptions of forms

The descriptions of application forms in OAC 310:~~00~~2-15 are presented to comply with the Oklahoma Administrative Procedures Act, ~~Title~~ 75 O.S. ~~Supp. 1997~~, ~~Section~~ § 302.

310:2-15-3. Uniform Employment Application for Nurse Aide Staff

(a) The application described in OAC 310:2-15-3 is required for use pursuant to ~~Title~~ 63 O.S. ~~Section~~ § 1-1950.4 and shall be used for the purposes set forth in that statute.

(b) ~~The uniform employment application shall *be used in the hiring of nurse aide staff by a nursing facility or a specialized facility as such terms are defined in the Nursing Home Care Act, a residential care home, as such term is defined by the Residential Care Act, an assisted living center as such term is defined by the Continuum of Care and Assisted Living Act, a continuum of care facility as defined by the Continuum of Care and Assisted Living Act, a freestanding hospice or program providing hospice services as such terms are defined by the Hospice Licensing Act, an adult day care center as such term is defined by the Adult Day Care Act, and a home care agency as defined by the Home Care Act. Such uniform application shall be used as the only application for employment of nurse aides in such facilities on and after January 1, 2001.* [63:1-1950.4]~~

~~(c)~~ The uniform employment application for nurse aide staff requires the following:

(1) personal information;
(2) employment desired;
(3) U.S. military record;
(4) prior work history;
(5) educational background;
(6) certification;

(7) references;
(8) background information;
(9) applicant's employment application certification and agreement;
~~(10)~~
~~(11)~~(10) previous certified nurse aide training;
~~(12)~~ (11) applicant's signature certifying no previous conviction and authorizing criminal history record checks; and
~~(13)~~ (12) Any additional information needed to answer all questions fully.

SUBCHAPTER 17. LOCAL PUBLIC HEALTH ENHANCEMENT GRANTS [REVOKED]

310:2-17-1. Purpose [REVOKED]

~~The rules of this Subchapter have been adopted for administering various grant programs for public health projects in Oklahoma. The rules describe the procedures that will be used to administer various local public health grant programs designed to improve the public health in Oklahoma's communities and rural areas. These rules are intended to be in full compliance with the Administrative Procedures Act and subsequent guidance related to funding of local projects.~~

310:2-17-2. Definitions [REVOKED]

~~The following words or terms used in this Subchapter shall have the meaning described below unless the context clearly indicates otherwise:~~

~~**"Commissioner"** means the head of the Oklahoma State Department of Health.~~

~~**"Department"** means the Oklahoma State Department of Health.~~

~~**"Deputy Commissioner"** means the head of a Division of the Oklahoma State Department of Health~~

~~**"Local project"** means the purpose for which an applicant requests funds under this grant program and does not cover any expenditure of funds through the competitive bidding process.~~

~~**"Review Committee"** means a committee established for the purpose of assisting with the grant application review process.~~

310:2-17-3. Contingency [REVOKED]

~~Implementation of a grant program is contingent upon funding being made available to the Department for this purpose.~~

310:2-17-4. Eligibility for grant program [REVOKED]

~~Applicants eligible for grants will be defined in the program guidelines and may include substate planning districts, non-profit organizations, educational institutions, local governments or other recognized political subdivisions, or others as appropriate and which exhibit a specific need related to the defined grant purpose. If federal grant funds are involved, applicants and grantees must agree to abide by all applicable federal requirements.~~

310:2-17-5. Grant description [REVOKED]

~~Grant funding may or may not require a local match. Matching requirements will be determined by the Department and will be prescribed in the program guidelines. In-kind matching may be accepted as a portion of the local match as described in the program guidelines. Grants which require a local match may be a reimbursement type grant where grantees make project expenditures, submit claims and receive reimbursement of the specified percentage of documented expenses up to the approved grant amount.~~

310:2-17-6. Grant program announcements [REVOKED]

~~(a) **Applicant notification.** The Department will notify potential applicants through direct mailings, news releases, personal contact and other appropriate means.~~

~~(b) **Announcement in *Oklahoma Register*.** A program announcement will be published in the *Oklahoma Register* in accordance with the Executive Order 95-26.~~

310:2-17-7. Grant program guidelines [REVOKED]

(a) **Program guidelines and application forms.** The Department will develop specific guidelines and application forms pertinent to the grant funding available and provide this information to potential applicants.

(b) **Application procedure.** Applicants will complete the application for funding according to the program guidelines and send completed applications to the Department's contact person as specified in the program guidelines.

(c) **Application deadline.** The application deadline will be established by the Department and published in the *Oklahoma Register* and program guidelines.

310:2-17-8. Grant limitations [REVOKED]

(a) **Funding range.** The funding range or limit for each application will be established by the Department and announced in the program guidelines. Partial funding of large projects may be considered.

(b) **Allowable expenses.** Allowable project expenses will generally include materials costs, worker salaries and other specific expenses as defined in the program guidelines or not prohibited by appropriate federal or state circulars or other provisions. In-kind service expenses may be allowable. Proper documentation of each expense is required, including paid invoices, canceled checks, payroll receipts, time records and other pertinent proof of expenditures.

(c) **Restrictions.** Grant funds must not replace currently funded projects and projects must occur in Oklahoma.

310:2-17-9. Application evaluation process [REVOKED]

(a) **Review and evaluation of applications.** Applications will be evaluated and ranked by a Review Committee established by the Department, Commissioner or Deputy Commissioner as appropriate to the funding source. The standard of review and selection of projects will be based upon the overall merit of the project as compared to other applications received. Applications with the highest evaluations will be recommended for funding to the extent of funds available.

(b) **Application evaluation criteria.** In anticipation of receiving applications for funding greater than the funds available, evaluation criteria will be used to rank the applications. These criteria will be developed by the Department, Commissioner, Deputy Commissioner and Review Committee and will be pertinent to the defined purpose of the grant funding.

310:2-17-10. Approval of grants [REVOKED]

(a) **Review Committee recommendation.** The Review Committee will recommend the final list of applicants to the Deputy Commissioner for funding consideration.

(b) **Commissioner approval.** The Deputy Commissioner will submit the final list of grantees and recommended amounts to the Commissioner for consideration. The Commissioner will review the recommendations of the review Committee and make the final decision on grant approvals and amounts within the limits of funding available.

310:2-17-11. Grant program administration [REVOKED]

(a) **Grant certification forms.** Upon approval, the Deputy Commissioner will distribute to all approved grantees the forms requiring grantee signature to certify the grant.

(b) **Grant award date.** The grant award date is the date the final purchase order is dated and filed. The Deputy Commissioner shall send each approved grantee a copy of the purchase order, which shall constitute official notification of grant approval. For reimbursement grants, expenditures made prior to the grant award date will not be considered for reimbursement.

(c) **Claims.** On reimbursement grants, grantees shall abide by standard state practices and program guidelines when submitting claims. Only documented expenses will be eligible for reimbursement and no

advance payments will be made. On other types of grants, claim procedures will be specified in the program guidelines.
(d) **Grant cutoff date.** Where appropriate, the Deputy Commissioner will establish the grant cutoff date when project expenditures must be completed.
(e) **Re-award of unclaimed funds.** The Department may re-award unclaimed grant funds to applications on file.
(f) **Cancellation of grants.** Grants may be canceled by the Department in the event of noncompliance or lack of progress by the grantee. Before canceling a grant, the Department will give the grantee thirty (30) days written notice and request information as to why the grant should not be canceled.
(g) **Record-keeping.** Grantees shall keep records related to the project for a period of at least three years. On request, grantees shall make these records available to the Department during this period, or until all audits are complete. Each grantee shall send the Deputy Commissioner a copy of any audit report which makes specific reference to the funded project.
(h) **Compliance audits.** The Department may audit completed grants funded under this program as appropriate.

SUBCHAPTER 19. PROCEDURES FOR DETERMINING AGENCY COST ALLOCATION TO THE CONSTRUCTION INDUSTRIES BOARD [REVOKED]

310:2-19-1. Purpose and authority [REVOKED]

The purpose of this chapter is to establish the procedures or methods used by the department to determine the annual allocation of administrative costs to the Construction Industries Board. Authority and obligation to establish such procedures is set forth in Chapter 426 of the 2001 Oklahoma Sessions Laws.

310:2-19-2. Definitions [REVOKED]

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

"Adjusted indirect cost agreement" means the agreement negotiated and reached with the Construction Industries Board utilizing the indirect cost agreement and adjusting or reducing it to reflect only those administrative cost centers that provide direct or identifiable benefits to the Construction Industries Board.

"Administrative cost centers" means those cost centers within the Department which provide services to each and every Department programs, whether in whole or in part.

"Cognizant agency" means the federal agency from which the Department receives the greatest majority of its federal funding.

"Commissioner of Health" and **"Commissioner"** mean the Oklahoma State Commissioner of Health, the chief executive officer of the Department. References in this subchapter to the Commissioner may include a designee of the Commissioner of Health. Designations shall be subject to such powers and limitations as are specified in writing.

"Construction Industries Board" means the Board having oversight over the Plumbing, Mechanical, Electrical and Inspector's Licensure programs and the power to enforce the provisions of the Plumbing License Law of 1955, the Oklahoma Inspectors Act, the Electrical License Act, and the Mechanical License Act.

"Department" means the Oklahoma State Department of Health.

"Indirect cost negotiation" means the process undertaken by the Department each fiscal period to obtain an approved overhead (indirect cost) rate through cooperation with the cognizant agency.

"Indirect cost agreement" means the agreement negotiated and reached with that federal agency from which the Department receives the greatest majority of its federal funding, defining and setting the overhead rate the department will utilize in the upcoming fiscal period in allocating the department's administrative expenses to programs administered by the Department.

"Revolving Fund" means the Plumbing Licensing Revolving Fund, the Electrical Revolving Fund, the Mechanical Licensing Revolving Fund, and/or the Oklahoma Inspectors Revolving Fund.

"Selected administrative cost centers" means those administrative cost centers within the Department whose services the Commissioner determines provides direct or identifiable benefits to the Construction Industries Board, including but not limited to, the Commissioner's Office, the Deputy (Director) of Administration, Financial Management, Procurement, Budget, Internal Services, Shipping & Receiving, Human Resources, Legal, Audit, Investigations, Communications and Minority Health.

310:2-19-3. Procedures and methods [REVOKED]

General. On or before April 15 of each year the Department shall, after conferring in good faith with the Construction Industries Board, enter into an agreement for the purpose of determining the portion of the Agency's total indirect costs to be allocated to the Construction Industries Board. In determining allocated indirect costs the Department must utilize that method of the two (2) methods set forth below that produces the least overall cost allocation to the Construction Industries Board.

(1) **Adjusted indirect cost agreement allocation method.** The Department's most current approved indirect cost agreement or rate is adjusted/reduced by removing those cost centers not included within the selected administrative cost centers, to create the adjusted indirect cost agreement. The resulting adjusted indirect cost agreement represents an adjusted overhead rate that shall be applied to the overall salary costs of the Construction Industries Board, by revolving fund, to arrive at the allocation of Department administrative costs to the particular revolving fund(s).

(2) **Direct allocation of actual administrative cost method.** The sum of the indirect costs incurred in the most recently completed fiscal year by a given cost center (i.e. each component or cost center within the selected administrative cost centers) is divided by that basis (e.g. total number of employees (FTEs) employed by the agency, total payroll of the agency, total number of discreet tasks performed, etc.) selected by the Commissioner as the most current and appropriate reflection of the average level of present service utilization of the given cost center by the Construction Industries Board, thereby deriving a unit cost for the services provided by the given cost center. The unit cost is then multiplied by the number of basis units applicable to the Construction Industries Board thereby deriving the aggregate indirect cost allocable to the Construction Industries Board for the given cost center. Each aggregate indirect cost allocation that is determined for each cost center identified as a component of the selected administrative cost centers is then totaled to yield the entire indirect cost allocation to be allocated by the Department to the Construction Industries Board and fixed, thereby, as the total indirect cost to be charged by the Department for the impending fiscal year. Additionally, any indirect cost item within a selected administrative cost center, specifically identifiable as a service or service component that is delivered or provided directly to the Construction Industries Board, shall be added to the annual fixed indirect cost charged by the Department and allocated to the Construction Industries Board within ninety (90) days of incurrence or identification.

310:2-19-4. Dissemination of the adjusted and indirect cost agreements [REVOKED]

The adjusted indirect cost agreement and the indirect cost agreement, together with any supporting documentation and evidence of how the indirect cost rate is reduced annually, shall be maintained within the Financial Management Service of the Department. A copy of the adjusted and indirect cost agreements and supporting documentation shall be provided upon request.

SUBCHAPTER 31. HUMAN SUBJECTS PROTECTION

310:2-31-1. General purpose

The Oklahoma State Department of Health (OSDH) 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~~ Oklahoma State

Department of Health (OSDH) Institutional Review Board (IRB) has been established to comply with federal regulations to protect the rights and welfare of human research participants in accordance with Title 45 of the Code of Federal Regulations Part 46 (45 C.F.R. Part 46). 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.~~

310:2-31-2. Scope

This subchapter applies to all individuals at the OSDH engaged in research involving human subjects. The Commissioner retains final authority to determine whether a particular activity is subject to this policy. This subchapter 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 (b) & (i) or 46.104(d), which is incorporated by reference in this subchapter.~~

310:2-31-3. Definitions [REVOKED]

~~The following words and terms, when used in this subchapter, 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.~~

~~"**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 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: 1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens or 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.~~

~~"**Inquiry**" means gathering information and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.~~

~~"**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.~~

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

~~"**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.~~

~~"**OHRP**" means the Office of Human Research Protections within the U.S. Department of Health and Human Services (DHHS) that is responsible for guidance, 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.~~

~~"**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.~~

~~"**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 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.~~

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

310:2-31-6. Authority of IRB

(a) All human subject research will be reviewed, prospectively approved, and subject to continuing oversight by the OSDH IRB.

(b) The OSDH IRB will have authority to approve, require modifications in, ~~or~~ disapprove, suspend or terminate the covered human subject research.

(c) ~~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.~~

~~(d)~~ The OSDH IRB will maintain IRB registration under the Office of Human Research Protections (OHRP) to permit the review of federally funded research.

310:2-31-7. IRB procedures

(a) All approved IRB research projects, whether approved by OSDH IRB or an external IRB, are subject to a review by OSDH ~~data use review board~~ Data Use Review Committee (DURC) to ensure release of OSDH data is allowable, limited to, and meets the statutory provisions pertaining to public health data sharing. ~~Data may or may not be released based on the data use review board's findings.~~ Release of data will be dependent on the DURC's findings.

(b) The OSDH and the OSDH IRB will established written procedures to ensure conformity with the requirements of 45 C.F.R. Part 46. ~~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) reviewing the informed consent process including documentation using the federal regulations and guidance from the Office of Human Research Protections;~~

~~(4) 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;~~

~~(5) 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~~

~~(6) 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.~~

~~(7) not allowing any member to 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; and~~

~~(8) inviting 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.~~

310:2-31-8. Training

~~(a)~~ The OSDH 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.

~~(b) The OSDH IRB will require documentation of such training from research investigators as a condition for conducting human subject research.~~

~~(c) 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.~~

~~(d) Members and staff of the IRB will complete relevant training before reviewing human subject research.~~

310:2-31-9. Compliance and knowledge of local context [REVOKED]

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

310:2-31-11. FDA regulated research [REVOKED]

~~The OSDH IRB will only review Food and Drug Administration (FDA) regulated research that has already been approved by an IRB that complies with FDA regulations.~~

310:2-31-12. Usage of procedures for allegation of possible misconduct in science

This section establishes procedure that will be followed when an allegation of possible misconduct in

science is received by an OSDH official. Procedures will be in accordance with 42 C.F.R. Part 93 and are subject to Office of Research Integrity (ORI) approval. Particular circumstances in an individual case may dictate variation from this procedure deemed in the best interests of OSDH and U.S. Public Health Service (PHS). Any change from these procedures also must ensure fair treatment to the subject of the inquiry or investigation. The Commissioner should approve any significant variation in advance.

310:2-31-13. Research Integrity Officer (RIO)

(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 OSDH 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~~ will keep ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential ~~DHHS~~ Department of Health and Human Services (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.

(e) The RIO has the responsibility under 42 C.F.R. Part 50 and 93 for the completion and submission of the institution's annual report to the federal ~~Office of Research Integrity~~ ORI.

310:2-31-14. 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.

310:2-31-15. 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 or a non-lawyer personal advisor (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal advisor to interviews or meetings on the case.

(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.

310:2-31-16. Deciding official

The Deciding Official (DO) 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~~ DO 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.

310:2-31-17. 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~~ RIO and will be counseled about appropriate procedures for reporting allegations.

310:2-31-18. 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, positions and reputations 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.~~

310:2-31-19. 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.~~

310:2-31-22. Conducting the inquiry

(a) **Initiation and purpose of the inquiry**. ~~Following the preliminary assessment, if~~ 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~~ they will immediately initiate the inquiry process. ~~In initiating the inquiry,~~ ~~the~~ The RIO should identify ~~clearly~~ the original allegation and any related issues that should be evaluated in the initial inquiry. 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~~ will be documented 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 ten (10 days) days of the initiation of the inquiry. The inquiry committee ~~shall~~ will 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~~ will notify the respondent of the proposed committee membership in ten (10 days). 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 five (5 days), days, the RIO ~~shall~~ will 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~~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.~~

310:2-31-23. 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.~~ A written inquiry report will be provided to ORI in accordance with the requirements in 42 CFR Part 93.309.

(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 fourteen (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.

310:2-31-24. Inquiry decision, notification, and confidentiality
(a) **Decision by ~~deciding official~~ DO**. ~~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~~ DO makes ~~this~~ a determination as to whether or not an investigation is justified. This determination~~, which~~ will be made within sixty (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~~ DO'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~~ DO'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.

310:2-31-26. 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~~ RIO 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~~ RIO, in consultation with other OSDH officials as appropriate, will appoint an investigation committee and the committee chair within ten (10) days of the notification to the respondent that an investigation is planned or as soon ~~thereafter~~ as practicable. The makeup of 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~~ will follow the same requirements outlined for the inquiry committee. ~~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~~ RIO will notify the respondent of the proposed committee membership within five (5) days. If the respondent submits a written objection to any appointed member of the investigation committee or expert, the ~~Research Integrity Officer~~ RIO 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~~ RIO 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~~ RIO, 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 and the determination that an investigation is warranted.~~, 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.

310:2-31-27. 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.~~ will be in accordance with the requirements in 42 C.F.R. Section 93.313 (Institutional investigation report).

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

(1) **Respondent**. After first redacting the identity of the whistleblower, the ~~Research Integrity Officer~~ RIO will provide the respondent with a copy of the redacted draft investigation report for comment and rebuttal. The respondent will be allowed five (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~~ RIO 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~~ RIO 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 IRB

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~~ DO 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~~ DO 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~~ DO may also return the report to the investigation committee with a request for further fact- finding or analysis. The ~~Deciding Official's~~ DO'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~~ RIO will notify both the respondent and the whistleblower in writing. In addition, the ~~Deciding Official~~ DO 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~~ RIO 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~~ DO, through the ~~Research Integrity Officer~~ RIO.

(e) **Time limit for completing the investigation report**. An investigation should ordinarily be completed with submission to ORI 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.~~

310:2-31-28. 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~~ RIO 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~~ RIO 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~~ RIO 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~~ RIO 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~~ RIO 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.

310:2-31-29. Institutional administrative actions

(a) OSDH will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated. If the ~~Deciding Official~~ DO determines that the alleged misconduct is substantiated by the findings, ~~he or she~~ they will decide on the appropriate actions to be taken, after consultation with the ~~Research Integrity Officer~~ RIO. 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~~ RIO will undertake reasonable efforts to restore the respondent's reputation if necessary. Depending on the particular circumstances, the ~~Research Integrity Officer~~ RIO 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~~ DO.

(d) Protection of the whistleblower and others. Regardless of whether the institution or ORI determines that scientific misconduct occurred, the ~~Research Integrity Officer~~ RIO 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~~ DO 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~~ RIO is responsible for implementing any steps the ~~Deciding Official~~ DO approves. The ~~Research Integrity Officer~~ RIO 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~~ DO 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~~ DO 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.

310:2-31-30. Record retention

After completion of a case and all ensuing related actions, the ~~Research Integrity Officer~~ RIO 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~~ RIO or committees. The ~~Research Integrity Officer~~ RIO 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. 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.