RULEMAKING ACTION:
Notice of proposed PERMANENT rulemaking

PROPOSED RULES:
Subchapter 3. General operations and procedures [AMENDED]
Subchapter 27. Contracts with charitable health care providers [AMENDED]
Subchapter 31. Human subjects protection [NEW]
Subchapter 35. Tanning facilities requirements [NEW]

SUMMARY:

SUBCHAPTER 3: GENERAL OPERATIONS AND PROCEDURES
The current rule within Subchapter 3 outlines the procedure and fees associated with requests for information and/or records pursuant to the Oklahoma Open Records Act, 51 O.S. §24A.1 et seq. The proposed rule changes modify the recommended method for submitting records requests, shorten the length of time before they are considered “abandoned,” and alters the fee schedule. The previous rule contained outdated fee information and did not provide adequate explanation of how fees are assessed.

SUBCHAPTER 27: CONTRACTS WITH CHARITABLE HEALTH CARE PROVIDERS
OAC 310:2-27 contains rules which establish eligibility criteria for charitable health care providers and medically indigent persons, procedures for entering into and revoking contracts between the Oklahoma State Department of Health or a city-county health department and a charitable health care provider and responsibilities and obligations pursuant to such contracts. The proposed rule changes update the length of malpractice claims history charitable providers would submit to the Department and modify the participation of the State Risk Management in certain program procedures.

SUBCHAPTER 31: HUMAN SUBJECTS PROTECTION
OAC 310:10, adopted in June 2002, incorporates by reference 45 CFR 46 (the Common Rule) and 42 CFR 50 (Research Integrity). Since adoption, a need to update stylistic and formatting aspects of the rule has been noted by the agency and partners. Additionally, upon review, it was determined that OAC 310:10 duplicates federal language and is duplicative between sections. It was also recommend that Chapter 10 be revoked in its entirety and moved to Chapter 2 as Subchapter 31. The revisions to this subchapter are anticipated to better protect human subjects (information or biospecimens) involved in research, while reducing burden, delay, and ambiguity for investigators.

The U.S. Department of Health and Human Services (HHS) and fifteen other Federal Departments and Agencies have issued final revisions to the Federal Policy for the Protection of Human Subjects (the Common Rule). A revision to OAC 310:10 is needed to align state rules with the federal changes. The concepts of identifiable information or biospecimens, technology, and related protections are not addressed. Moreover, the revised 45 CFR 46 specifically addresses public health authority and public health surveillance.

SUBCHAPTER 35: TANNING FACILITIES REQUIREMENTS
The proposed rule changes to this subchapter, if adopted, implement the agency's requirements from SB765 (2017), codified at 63 O.S. § 7302 et seq., and effective on November 1, 2017. The proposed rules would prohibit the use of tanning facilities by persons under eighteen (18) years of age and require signage to be posted.
AUTHORITY:
Commissioner of Health, 63 O.S. § 1-104; 51 O.S. § 24A.1 et seq., 51 O.S. § 151 et seq.,
63 O.S. § 7302 et seq.;

COMMENT PERIOD:
February 15, 2019, through March 21, 2019. Persons wishing to make comments may do so in
person, by mail, or by email through March 21, 2019 at: Oklahoma State Department of Health,
Attn: Agency Rules Liaison, Health Policy, Partnerships and Planning. 1000 Northeast Tenth Street,
Oklahoma City, OK 73117-1207, or OSDHRules@health.ok.gov

PUBLIC HEARING:
Pursuant to 75 O.S. § 303 (A), the public hearing for the proposed rulemaking in this chapter
shall be on March 19, 2019, at the Oklahoma State Department of Health, 1000 N.E. 10th Street,
Oklahoma City, OK 73117-1207, in Room 1102 beginning at 10am. In the event of state offices
closing due to inclement weather, there will be an alternate hearing date on March 21, 2019, at
the same location in room 1102 beginning at 10am.

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
March 21, 2019.

COPIES OF PROPOSED RULES:
The proposed rules may be obtained for review from the contract person identified below or via
the agency website at www.health.ok.gov.

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.health.ok.gov.

CONTACT PERSONS:
Spencer Kusi, Agency Rule Liaison, Oklahoma State Department of Health, 1000 N.E. 10th
Street, Oklahoma City, OK 73117-1207; e-mail OSDHRules@health.ok.gov
INITIAL RULE IMPACT STATEMENT
(This document may be revised based on comment received during the public comment period.)

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

1. DESCRIPTION: (a brief description of the purpose of the proposed rule [75 O.S. §303.D(2)(a)])

SUBCHAPTER 3: GENERAL OPERATION AND PROCEDURES

The current rule within Subchapter 3 outlines the procedure and fees associated with requests for information and/or records pursuant to the Oklahoma Open Records Act, 51 O.S. §24A.1 et seq. The proposed rule changes modify the recommended method for submitting records requests, shortens the length of time before they are considered “abandoned,” and alters the fee schedule. The previous rule contained outdated fee information and did not provide adequate explanation of how fees are assessed.

SUBCHAPTER 27 APPLICATIONS FOR CHARITABLE PROVIDERS

The Oklahoma Volunteer Charitable Healthcare Provider Program (OVCHPP) offers state tort immunity from liability to health care providers who provide care to medically indigent persons at a free clinic, and who are working within the scope of employment of a charitable health care provider. The OVCHPP also offers healthcare providers state tort immunity from liability in instances where a patient is referred from a free clinic to another charitable healthcare provider for medical services. The rules of Subchapter 27 are adopted to implement Senate Bill 930 (2007), as codified at 51 O.S. § 151 et seq., for the administration of contracts between charitable health care providers and the Oklahoma State Department of Health or a city-county health department for the benefit of Oklahoma residents who are medically indigent. OAC 310:2-27 contains rules which establish eligibility criteria for charitable health care providers and medically indigent persons, procedures for entering into and revoking contracts between the Oklahoma State Department of Health or a city-county health department and a charitable health care provider and responsibilities and obligations pursuant to such contracts. The proposed rule changes update the length of malpractice claims history charitable providers would submit to the Department and modify the participation of the State Risk Management in certain program procedures.

SUBCHAPTER 31 HUMAN SUBJECTS PROTECTION

OAC 310:10, adopted in June 2002, incorporates by reference 45 CFR 46 (the Common Rule) and 42 CFR 50 (Research Integrity). Additionally, OAC 310:10 was adopted in 2002 when the style and formatting of rules was different. Upon review, it was determined that OAC 310:10 duplicates federal language and is duplicative between sections. It was also recommend that Chapter 10 be revoked in its entirety and moved to Chapter 2 as Subchapter 31. The revisions to this subchapter are anticipated to better protect human subjects (information or biospecimens) involved in research, while reducing burden, delay, and ambiguity for investigators. The U.S. Department of Health and Human Services (HHS) and fifteen other Federal Departments and Agencies have issued final revisions to the Federal Policy for the Protection of Human Subjects (the Common Rule). A final rule was published in the Federal Register (FR) on January 19, 2017, and was amended to delay the effective and compliance dates on January 22, 2018 and June 19, 2018. The revised Common Rule is effective July 19, 2018; additionally from July 19, 2018 through January 20, 2019 institutions are not permitted to implement the entirety of the revised Common Rule. The revisions to the Common Rule include Institutional Review Board (IRB) operations, informed consent, scope of human subjects research, guidelines for exemptions, and compliance dates. A revision to OAC 310:10 is needed to align with the federal changes. The concepts of identifiable information or biospecimens, technology, and
related protections are not addressed. Moreover, the revised 45 CFR 46 specifically addresses public health authority and public health surveillance.

SUBCHAPTER 35 TANNING FACILITIES REQUIREMENTS

The proposed rule changes to this subchapter, if adopted, implement the agency's requirements from SB765 (2017), codified at 63 O.S. § 7302 et seq., and effective on November 1, 2017. The proposed rules would prohibit the use of tanning facilities by persons under eighteen (18) years of age and require signage to be posted.

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE: (a description of the classes of persons who most likely will be affected by the proposed rule, including classes that will bear the costs of the proposed rule, and any information on cost impacts received by the agency from any private or public entities [75 O.S. §303.D(2)(b)]

SUBCHAPTER 3: GENERAL OPERATION AND PROCEDURES

Fee changes would affect persons requesting records pursuant to the Oklahoma Open Records Act. The change would not affect requestors acting the public interest, including media outlets. Changes to the length of time for a request to be deemed “abandoned” would apply to all requests.

SUBCHAPTER 27 APPLICATIONS FOR CHARITABLE PROVIDERS

Medically indigent "means a person requiring medically necessary hospital or other health care services for the person or the dependents of the person who has no public or private third-party coverage, and whose personal resources are insufficient to provide for needed health care. OVCHHP is an incentive to providers to volunteer their time and expertise at no charge to the medically indigent with tort immunity; thus supporting access to care and improving health outcomes for those served. In addition, OVCHPP lessens the liability and cost to charitable clinics across the state. The cost of the premium to OSDH is dependent on the number of FTE or volunteer hours provided. OSDH only pays the premium if a claim is filed.

SUBCHAPTER 31 HUMAN SUBJECTS PROTECTION

The proposed administrative rule changes to this subchapter apply to any person paid by, under the control of, or affiliated with OSDH, such as scientists, contractors, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators. The Commissioner retains final authority to determine whether a particular activity is subject to these rules.

SUBCHAPTER 35 TANNING FACILITIES REQUIREMENTS

Those classes of persons most likely to be affected by the proposed rule changes to this subchapter include owners and operators of tanning facilities in Oklahoma. The costs of compliance of these rules will be to the owners and operators of the tanning facilities through indirect costs such as posting required signage and revenue loss due to the prohibition of persons under eighteen (18) years of age using the facilities.

Persons under eighteen (18) years of age who would potentially utilize tanning facilities will also be affected due to their inability to access the facilities.

3. DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES: (a description of the classes of persons who will benefit from the proposed rule [75 O.S. § 303(D)(2)(c)])

SUBCHAPTER 3: GENERAL OPERATION AND PROCEDURES
Stakeholders in agency services would benefit from a more efficient records request process. Members of the news media, nonprofit organizations and the general public comprise common stakeholders requesting records of the Department.

SUBCHAPTER 27 APPLICATIONS FOR CHARITABLE PROVIDERS

Medically indigent "means a person requiring medically necessary hospital or other health care services for the person or the dependents of the person who has no public or private third-party coverage, and whose personal resources are insufficient to provide for needed health care". OVCHHP is an incentive to providers to volunteer their time and expertise at no charge to the medically indigent with tort immunity; thus supporting access to care and improving health outcomes for those served. In addition, OVCHPP lessens the liability and malpractice cost to charitable clinics across the state.

SUBCHAPTER 31 HUMAN SUBJECTS PROTECTION

These proposed changes to administrative rules benefit those who participate in OSDH programs or conduct surveillance of reportable conditions. A multitude of OSDH services are supported through HHS funding or conduct human subjects research as a part of program evaluation or in determination of risk factors or sequelae from exposures to environmental or biological exposures. The revisions are anticipated to better protect human subjects (information or biospecimens) involved in research, while reducing burden, delay, and ambiguity for investigators.

SUBCHAPTER 35 TANNING FACILITIES REQUIREMENTS

The potential benefit will be to persons under eighteen (18) years of age who will have reduced health risks associated with tanning including, but are not limited to, skin cancer, premature aging of skin, burns to the skin, and adverse reactions to certain medications, foods, and cosmetics. The Department will track and determine potential benefits through established surveillance systems, such as the Oklahoma Central Cancer Registry.

4. ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES: (a description of the probable economic impact of the proposed rule upon affected classes of persons or political subdivisions, including a listing of all fee changes and, whenever possible, a separate justification for each fee change [75 O.S. §303(D)(2)(d)])

SUBCHAPTER 3: GENERAL OPERATION AND PROCEDURES

There are no implementation costs or costs of compliance to the proposed changes to this subchapter. A review of records requests does not show that any fees have been collected by the agency in recent years. Because public interest requests are exempted from fees, the impact on records requesters would be negligible. There is no anticipated impact on political subdivisions.

SUBCHAPTER 27 APPLICATIONS FOR CHARITABLE PROVIDERS

No economic impacts or fee changes are anticipated for the proposed changes to this subchapter.

SUBCHAPTER 31 HUMAN SUBJECTS PROTECTION

No impacts on political subdivisions are anticipated for the proposed changes to this subchapter.

SUBCHAPTER 35 TANNING FACILITIES REQUIREMENTS

While the costs to the owners and operators of tanning facilities is unknown at the present time, it is assumed there will be minimal costs to the owners and operators if the proposed rules are adopted.
Necessary time and equipment will be needed to print and post the required signage. There is a potential for revenue loss due to persons under eighteen (18) years of age being prohibited from using the tanning facilities.

5. **COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:**
   (the probable costs and benefits to the agency and to any other agency of the implementation and enforcement of the proposed rule, the source of revenue to be used for implementation and enforcement of the proposed rule, and any anticipated effect on state revenues, including a projected net loss or gain in such revenues if it can be projected by the agency [75 O.S. §303(D)(2)(e)])

SUBCHAPTER 3: GENERAL OPERATION AND PROCEDURES
   There would be no implementation costs for the proposed changes to this subchapter. The proposed rules will be implemented and enforced by existing Department personnel and will have no anticipated effect on state revenues.

SUBCHAPTER 27 APPLICATIONS FOR CHARITABLE PROVIDERS
   There is not an anticipated cost to the Department to implement the changes, as existing staff and operating costs will cover all aspects of rule drafting and implementation. No additional funds for anticipation and enforcement are required.
   By requesting an applicant's claims history for the last 10 years as opposed to 5 years, OSDH can make a more informed decision to determine risk and thus whether or not to award a charitable provider contract; as well as a better determination of the amount of the insurance premium the department would be required to pay into the State's self-insurance in relation to the risk.

SUBCHAPTER 31 HUMAN SUBJECTS PROTECTION
   The proposed rules will be implemented and enforced by existing Department personnel and will have no anticipated effect on state revenues.

SUBCHAPTER 35 TANNING FACILITIES REQUIREMENTS
   The cost to implement the proposed rules for the Department is unknown at the present time.

6. **IMPACT ON POLITICAL SUBDIVISIONS:** (a determination of whether implementation of the proposed rule will have an economic impact on any political subdivisions or require their cooperation in implementing or enforcing the rule [75 O.S. §303.D.2(f)])

SUBCHAPTER 3: GENERAL OPERATION AND PROCEDURES
   There are no implementation costs or costs of compliance to the proposed changes to this subchapter. A review of records requests does not show that any fees have been collected by the agency in recent years. Because public interest requests are exempted from fees, the impact on records requesters would be negligible. There is no anticipated impact on political subdivisions.

SUBCHAPTER 27 APPLICATIONS FOR CHARITABLE PROVIDERS
   No economic impacts or fee changes are anticipated for the proposed changes to this subchapter. No impacts on political subdivisions are anticipated for the proposed changes.

SUBCHAPTER 31 HUMAN SUBJECTS PROTECTION
   There will be no significant economic impact to internal or external researchers due to the proposed changes to this subchapter. The Department does not charge or collect any fees associated with this
proposed changes to this subchapter. There will be no direct impact on any political subdivision as a result of implementing or enforcing the proposed changes to this subchapter of rule.

SUBCHAPTER 35 TANNING FACILITIES REQUIREMENTS
While the costs to the owners and operators of tanning facilities is unknown at the present time, it is assumed there will be minimal costs to the owners and operators if the proposed rules are adopted. Necessary time and equipment will be needed to print and post the required signage. There is a potential for revenue loss due to persons under eighteen (18) years of age being prohibited from using the tanning facilities.

7. **ADVERSE EFFECT ON SMALL BUSINESS:** *(a determination of whether implementation of the proposed rule may have an adverse economic effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act [75 O.S. §303(D)(2)(g)])*

SUBCHAPTER 3: GENERAL OPERATION AND PROCEDURES
There is no anticipated negative effect on small businesses from the proposed changes to this subchapter. The proposed changes seek to remove outdated means of distributing records requests, to facilitate more efficient processing of inquiries.

SUBCHAPTER 27 APPLICATIONS FOR CHARITABLE PROVIDERS
Implementation of the proposed changes to this subchapter should have no adverse effect on small businesses as provided by the Oklahoma Small Business Regulatory Flexibility Act.

SUBCHAPTER 31 HUMAN SUBJECTS PROTECTION
Implementation of the proposed changes to this subchapter should have no adverse effect on small businesses as provided by the Oklahoma Small Business Regulatory Flexibility Act.

SUBCHAPTER 35 TANNING FACILITIES REQUIREMENTS
Tanning facilities are not currently licensed in Oklahoma making it unknown how many facilities are associated with small business. While the cost to the owners and operators of tanning facilities is unknown at the present time, it is assumed there will be minimal costs to the owners and operators if the proposed rule changes to this subchapter are adopted.

8. **EFFORTS TO MINIMIZE COSTS OF RULE:** *(an explanation of the measures the agency has taken to minimize compliance costs and a determination of whether there are less costly or nonregulatory methods or less intrusive methods for achieving the purpose of the proposed rule [75 O.S. § 303(D)(2)(h)])

SUBCHAPTER 3: GENERAL OPERATION AND PROCEDURES
There are no costs identified with the proposed changes to this subchapter. The proposed changes seek to remove outdated means of distributing records requests, to facilitate more efficient processing of inquiries.

SUBCHAPTER 27: APPLICATIONS FOR CHARITABLE PROVIDERS
No additional costs are associated with the proposed changes to the rule subchapter. By having an increased risk history of charitable providers documented, it may reduce the risk to the state and thus produce slight savings.

SUBCHAPTER 31: HUMAN SUBJECTS PROTECTION
No methods of lesser costs of the rule have been identified for the proposed changes to this subchapter.
SUBCHAPTER 35: TANNING FACILITIES REQUIREMENTS

There has been no effort to minimize compliance costs, as all the requirements contained in the proposed rule changes to this subchapter are required by the implementing statutory requirements. The proposed rules support the core public health function of policy development as well as ensures the delivery of the essential public health services of (1) informing, educating, and empowering people about health issues, (2) developing policies and plans that support individual and community health efforts, and (3) enforcing laws and regulations that protect health and ensure safety. Indoor tanning increases a person’s risk of skin cancer and is especially risky for young people. A person’s risk of skin cancer increases with each indoor tanning session and is highest among those who start tanning at a younger age.

9. EFFECT ON PUBLIC HEALTH AND SAFETY: (a determination of the effect of the proposed rule on the public health, safety and environment and, if the proposed rule is designed to reduce significant risks to the public health, safety and environment, an explanation of the nature of the risk and to what extent the proposed rule will reduce the risk [75 O.S. §303(D)(2)(i)])

SUBCHAPTER 3: GENERAL OPERATION AND PROCEDURES

There is no anticipated effect on public health and safety for the proposed changes to this subchapter.

SUBCHAPTER 27: APPLICATIONS FOR CHARITABLE PROVIDERS

OVCHHP is an incentive to providers to volunteer their time and expertise at no charge to the medically indigent with limited risk; thus supporting access to care and improving health outcomes. In addition, OVCHPP lessens the liability and cost to charitable clinics across the state. Many of these clinics are supported by volunteers and have limited resources. By better clarifying the role of State Risk Management and OSDH and having a longer claims history of applicants, the department can support the health and safety of patients when determining a contract award to a provider in regard to risk.

SUBCHAPTER 31: HUMAN SUBJECTS PROTECTION

The proposed rule changes to this subchapter are required to adjust to the changing landscape of regulations and rules dealing with human subjects research and to align the Department’s rules with current federal regulations. The revisions are anticipated to better protect human subjects (information or biospecimens) involved in research, while reducing burden, delay, and ambiguity for investigators. Furthermore, without the rules changes, federal funding from HHS may be in jeopardy.

SUBCHAPTER 35: TANNING FACILITIES REQUIREMENTS

The proposed rule changes to this subchapter support the core public health function of policy development as well as ensures the delivery of the essential public health services of (1) informing, educating, and empowering people about health issues, (2) developing policies and plans that support individual and community health efforts, and (3) enforcing laws and regulations that protect health and ensure safety. Indoor tanning increases a person’s risk of skin cancer and is especially risky for young people. A person’s risk of skin cancer increases with each indoor tanning session and is highest among those who start tanning at a younger age. Further evidence of the increased risk can be found at the following link: https://www.cdc.gov/cancer/skin/pdf/indoor_tanning_brief.pdf

10. DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION: (a determination of any detrimental effect on the public health, safety and environment if the proposed rule is not implemented [75 O.S. § 303(D)(2)(j)]
SUBCHAPTER 3: GENERAL OPERATION AND PROCEDURES
There is no anticipated measureable effect on public health and safety without adoption of the proposed changes to this subchapter.

SUBCHAPTER 27: APPLICATIONS FOR CHARITABLE PROVIDERS
OVCHPP may see a reduced number of healthcare providers willing to volunteer their services without the state tort immunity protection. As a result, access to care could be limited to those with the fewest resources to obtain it.

SUBCHAPTER 31: HUMAN SUBJECTS PROTECTION
Without the rule change to this subchapter, the administrative rule that sets forth the ethical principles for safeguarding the rights and welfare of human beings recruited to participate in research activities remains as it existed 20 years ago. The concepts of identifiable information or biospecimens, technology, and related protections would remain unaddressed in state administrative rule. Moreover, the revised 45 CFR 46 specifically addresses public health authority and public health surveillance, which are not addressed in the pre-2017 version. Without the rule change to this subchapter, federal funding from HHS may be in jeopardy.

SUBCHAPTER 35: TANNING FACILITIES REQUIREMENTS
Without the rule change to this subchapter, persons under eighteen (18) years of age may continue to have access to tanning facilities and therefore be exposed to the health risks associated with tanning including, but are not limited to, skin cancer, premature aging of skin, burns to the skin, and adverse reactions to certain medications, foods, and cosmetics.

11. PREPARATION AND MODIFICATION DATES: (the date the rule impact statement was prepared and if modified, the date modified [75 O.S. § 303(D)(2)(k)])

SUBCHAPTER 3: GENERAL OPERATION AND PROCEDURES
This rule impact statement was prepared on December 12, 2018. No modifications were made subsequent to the publication of the Notice of Rulemaking Intent were made.

SUBCHAPTER 27 APPLICATIONS FOR CHARITABLE PROVIDERS
This rule impact statement was prepared on December 12, 2018. No modifications were made subsequent to the publication of the Notice of Rulemaking Intent were made.

SUBCHAPTER 31 HUMAN SUBJECTS PROTECTION
This rule impact statement was prepared on December 12, 2018. No modifications were made subsequent to the publication of the Notice of Rulemaking Intent were made.

SUBCHAPTER 35 TANNING FACILITIES REQUIREMENTS
This rule impact statement was prepared on December 12, 2018. No modifications were made subsequent to the publication of the Notice of Rulemaking Intent were made.
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 subject to inspection and mechanical reproduction under the provisions set forth below.

(c) Initial procedural requirements. A request for inspection may be submitted orally, electronically or in writing. To encourage a fully articulated and accurate response to a request, OSDH recommends a request be submitted in a via its online form that is susceptible to memorialization such as a writing, electronic mail or facsimile transmission, and must that the requester 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 with the OORA, agency personnel determine that a search is necessary to gather and collect the records sought by the requester, 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 filed submitted in accordance with these rules. After a determination is made of the estimated search time any fees necessary to gather the records requested, the agency will remit an advice of the cost to the requester. 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 sixty (thirty (60)30) days shall be deemed abandoned.

(g) Appeal. If the agency cannot comply with the request for disclosure, the requester shall be notified in writing of the adverse determination, stating the reason(s) therefor and advising the requestor of the right
to an administrative appeal under the provisions of subparagraph 310:2-3-7.

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

(1) Paper Records
   (A) Regular Copy - $0.25 per page
   (B) Certified Copy - $1.00 per page
   (C) Copy Sent by Fax - $0.35 per page
   (D) Copy of Pages Larger than 8-1/2 X 14 - $0.50 per page

(2) Audio Tapes
   (A) With Tape Provided - $5.00 per tape
   (B) Without Tape Provided - $10.00 per tape

(3) Electronic Records - If request is for records to be produced in a format other than an electronically transmitted digital file, Requester is required to furnish blank tape(s) if reproduction is not in a printout format, and reimburse the agency for the actual cost of the use of the central processing unit of any computer used to access data stored therein. The agency will recoup the actual cost of transferring the records to the requester’s media.
   (A) $50.00 per hour programming time
   (B) $50.00 per hour for other computer time

(4) Search Other Fees - $25.00 per hour for requests that are solely for commercial purpose or that cause excessive disruption of the agency’s essential functions. “Excessive disruption” fees apply to requests that require more than eight (8) hours of actual employee work time to compile.

SUBCHAPTER 27. CONTRACTS WITH CHARITABLE HEALTH CARE PROVIDERS

310:2-27-4. Application to contract as a charitable health care provider
(a) The Department shall develop and provide an application form for a person to use when applying with a contracting agency to enter into a charitable provider contract.

(b) A person may apply to enter into a charitable provider contract as a charitable health care provider if such applicant:
   (1) is licensed, certified, or otherwise authorized by the laws of Oklahoma to administer, in the ordinary course of business or in the practice of a profession, the health care that is the subject of the charitable health care contract;
   (2) will provide health care to the medically indigent, as defined in section 310:2-27-2; and
   (3) submits a complete application to a contracting agency requesting to enter into a charitable provider contract, and the application must include:
      (A) the scope of service the applicant will provide to the medically indigent; and
      (B) the applicant's claims history for the last five (5) ten (10) years.
(c) The claims history of the applicant will be reviewed by Risk
Management to determine the amount of the insurance premium the Department would be required to pay into the State's self-insurance pool. This assessment shall be considered by the contracting agency when determining if the applicant will be awarded a charitable provider contract. State Risk Management will determine the amount of the insurance premium the Department would be required to pay into the State's self-insurance pool and manage claims related to the program, if and when they occur. State Risk Management will determine the amount of the insurance premium the Department would be required to pay into the State's self-insurance pool and manage claims related to the program, if and when they occur.

(d) A health care provider whose application to be granted a charitable provider contract from a contracting agency is denied may re-submit the application with a different scope of service.

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 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 ongoing 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
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.

"OHCHR" 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.

310:2-31-4. Incorporations by reference
(a)This subchapter 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 subchapter hereby incorporates by reference Part 50 and 93 of Title 42 of the Code of Federal Regulations (42 C.F.R. Parts 50 and 93) as if fully set forth herein.
310:2-31-5. 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.

(c) Information provided under the Federalwide Assurance will be updated on schedule in order to maintain an active Assurance.

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 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 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 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.

(b) The OSDH and the OSDH IRB will established 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) 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.

(6) 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

(7) 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
The IRB will ensure that it has appropriate knowledge of the local context in which research for which it is responsible will be conducted.

310:2-31-10. 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.

310:2-31-11. FDA regulated research
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. 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 should approve any significant variation in advance.

### 310:2-31-13. 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.

(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.

### 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.

(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 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.

310:2-31-17. 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 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 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.

310:2-31-20. 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.

310:2-31-21. 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.

310:2-31-22. 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.

310:2-31-23. 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.
(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.

310:2-31-24. 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.

310:2-31-25. 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.

310:2-31-26. 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 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.

310:2-31-27. 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.

(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 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 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.

310:2-31-28. 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 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.

310:2-31-29. Institutional administrative actions

(a) OSDH will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated. If the Deciding Official 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.

310:2-31-30. 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. 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.

**SUBCHAPTER 35. TANNING FACILITIES REQUIREMENTS**

**310:2-35-1. Purpose**

This Chapter applies to tanning facilities and their owners or operators. The rules are to implement the provisions of 63 O.S. Section 7302.

**310:2-35-2. Sign contents for entrances to tanning rooms or tanning establishments**

(a) At least one (1) sign shall be posted in a place readily visible to persons entering a facility where a tanning device is operated. The sign shall be black text on white or other highly visible contrasting colors and include the language provide in 63 O.S. § 7302(C) in letters at least 1/2 inch high. The sign shall have dimensions not less than 8 1/2 inches by 11 inches.

(b) Signs shall have the following statements:

(1) It is unlawful for a tanning facility or operator to allow a person under eighteen (18) years of age to use any tanning device;

(2) A tanning facility or operator that violates the provision shall be subject to a civil penalty;

(3) An individual may report a violation of one or more provisions to the local law enforcement agency; and

(4) The health risks associated with tanning include, but are not limited to, skin cancer, premature aging of skin, burns to the skin, and adverse reactions to certain medications, foods, and cosmetics.

(c) Signs shall be in place within 30 days of the effective date of these rules.

**310:2-35-3. Unlawful act**

It shall be unlawful for any person under eighteen (18) years of age to use any tanning device of any tanning facility in this state.

**310:2-35-4. Signage**

For any tanning facility, the owner, operator or lessee shall see that signage is posted as required in this Subchapter.