TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 551. ADVANCEMENT IN STEM CELL CURES AND THERAPIES ACT

RULEMAKING ACTION:
PERMANENT final adoption
RULES:
Subchapter 3. Required Information for Reporting
310:551-3-2 [NEW]
310:551-3-3 [NEW]
Subchapter 5. Confidentiality of Information and Responsibilities of Information Providers
310:551-5-1 [NEW]
310:551-5-2 [NEW]
310:551-5-3 [NEW]
310:551-5-4 [NEW]
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Oklahoma State Board of Health, Title 63 O.S. Section 1-104; 63 O.S. § 1-270.2
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Subchapter 3. Required Information for Reporting
310:551-3-2 [NEW]
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ANALYSIS:
The proposed rule will make permanent sections of the rules that are currently implemented by emergency rule. These rules will enable the State Health Department to implement the reporting process for stem cell research studies as specified in 63 O.S. Supp 2008, § 1-270.2.

PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTION 308.1(A) WITH AN EFFECTIVE DATE OF July 25, 2010:

SUBCHAPTER 3. REQUIRED INFORMATION FOR REPORTING

310:551-3-2. Data files
(a) When a data file is received from an information provider, the Department will notify the information provider acknowledging receipt of the data.
(b) Every data file received by the Department will be processed and checked for errors. This process will include error checking for out of range, or invalid data elements as specified in Section 310:551-3-1. Upon processing the submitted data file, the Department will send the information provider:
(1) An acknowledgement that the report appears to be without any apparent error, or,
(2) A list of errors in that information provider's data file along with a request to correct the listed errors within 30 days of receipt of the notice.

310:551-3-3. Periodic schedule for submission of information
(a) Information providers must submit their data files to the Department within thirty (30) days of beginning the research, thirty (30) days of completion of the research, or by October 1, whichever is soonest.
(b) The Department may grant an extension of the reporting deadline upon written request from the information provider made at least ten (10) days prior to the deadline and supported by substantial cause.

SUBCHAPTER 5. CONFIDENTIALITY OF INFORMATION AND RESPONSIBILITIES OF INFORMATION PROVIDERS

310:551-5-1. Confidentiality
(a) All information collected from any source will remain confidential in accordance with 51 O.S. § 24A.19, and will not be deemed or treated as a public record as otherwise defined in the Open Records Act. Under

no circumstances shall information submitted to the Department pursuant to this Chapter be used for any purpose other than the compilation of data to be transmitted to the Governor, Speaker of the Oklahoma House of Representatives and the President Pro Tempore of the State Senate. The information collected pursuant to this Chapter may not be released voluntarily or in response to any legal process unless the Department is directed to release it by a court of competent jurisdiction, granted after application showing good cause.

(b) The Department will develop internal procedures to ensure that the collection, maintenance and dissemination of the information collected is in compliance with all provisions of state and federal laws and regulations, including this Chapter.

310:551-5-2. Release and dissemination of information upon request

After approval by the Department, aggregate compilations prepared for release or dissemination from the data collected shall be public record. However, reports prepared at the request of an individual information provider containing information concerning only its transactions, shall not be public record.

310:551-5-3. Responsibilities of information providers

Information providers shall be responsible to insure that the information required by this Chapter to be reported to the Department is timely collected and reported to the Department and that the data reported is accurate and complete. The obligation to report may be satisfied by the IRB or Stem Cell Research Oversight Committee of the person or entity conducting stem cell research.

310:551-5-4. Reporting safety and ethical violations

It shall be the obligation of the IRB or Stem Cell Research Oversight Committee to report any violation of a safety or ethical standard that has not be corrected within thirty (30) days. The report of an uncorrected violation of a safety or ethical standard must be made to the Department within (60) days of occurrence or by October 1, whichever is sooner.