Kansas Administrative Regulations

Department of Health and Environment

Article 70.—Cancer Registry

28-70-4. Confidential data for follow-up patient studies.

(a) For the purposes of this regulation, the following definitions shall apply:

(1) "Institutional review board" means an institutional review board established and conducted pursuant to 45 CFR 46.101 through CFR 46.117, as revised on October 1, 2008.

(2) "Person" shall mean a state university, a state agency, or a county health department.

(b) Each person with a proposal for a follow-up cancer study ("study") shall submit the proposal to each of the following for approval before the commencement of the study:

(1) The person's institutional review board;

(2) the department's health and environmental institutional review board;

(3) the university of Kansas medical center's institutional review board; and

(4) the cancer registry data release board.

(c) Each study not approved by each board specified in subsection (b) shall be returned to the person for revisions. Any unapproved study may be resubmitted to each board.

(d) After receiving the approvals required in subsection (b) and before commencing the study, the person proposing the study shall submit the proposal for the study to the secretary or the secretary's designee for approval.

(e) Each person conducting an approved study shall reimburse the cancer registry for all costs pertaining to the retrieval of confidential data. The cancer registry shall be credited by the person on any publication or presentation when the cancer registry data is used.

(f) Before proceeding with each study, the cancer registry director shall obtain informed consent from each individual who is the subject of the data or from that

individual's parent or legal guardian. The consent form shall accompany or follow the notice specified in subsection (g). Signing the consent form shall indicate that the individual has read and understands the information provided in the notice.

(g) The cancer registry director shall deliver a notice to each subject individual or the subject individual's parent or legal guardian. Each notice shall include the following information:

(1) All details of the study to be conducted, including the purpose, methodology, and public health benefit; and

(2) the following information:

(A) Participation in the study is voluntary;

(B) the method of data collection will be at the convenience of the subject individual. Data will be collected in writing, by telephone, or by personal interview; and

(C) the subject individual will be provided with a summary of the final report of the study.

(Authorized by and implementing K.S.A. 2008 Supp. 65-1,172; effective June 12, 2009.)