

3701-4-03 Confidentiality; research.

- (A) Any information, data, and reports with respect to a case of cancer which are furnished to, or procured by, the department shall be confidential and shall be used only for public health surveillance and research for the purposes of reducing the morbidity or mortality of cancer.
- (B) A person involved with a research project may be given access to confidential information if all the following conditions are met and if the research project is approved by the department's institutional review board:
 - (1) The person conducting the research submits verification of his credentials and of the credentials of other individuals involved in conducting the research;
 - (2) The person conducting the research provides written information about the purpose of the research project, the nature of the data to be collected and how the researcher intends to analyze it, the records the researcher seeks to review, and the safeguards the researcher will take to protect the identity of patients whose records the researcher will be reviewing;
 - (3) The proposed safeguards are adequate to protect the identity of each patient whose records will be reviewed. Safeguards for the protection of the identity of patients shall include, but are not limited to, provisions to limit access to identifying data to only those individuals who during the course of the project need access to such information for research purposes and provisions for the maintenance and/or destruction of identifying information after the termination of the project;
 - (4) An agreement is executed between the department and the researcher that specifies the terms of the researcher's use of the records. The agreement will prohibit the publication or release of protected health information.
- (C) Notwithstanding paragraphs (A) and (B) of this rule, a researcher may, with the approval of the department's institutional review board, contact individual cancer patients to request additional information for research purposes or to solicit a patient's participation in a research project. The researcher shall first notify the patient's managing physician of the intent to contact the patient. Unless the patient's managing physician informs the researcher within a reasonable time that the patient should not be contacted, the researcher may contact the patient. The researcher shall obtain the patient's verbal or written consent prior to requesting additional information or including the patient in a research project.
- (D) Notwithstanding paragraphs (A) and (B) of this rule the department may release confidential information concerning individual cancer patients who are not Ohio residents to the cancer registry of the patient's state of residence at diagnosis.
- (E) Nothing in this rule prevents the release to any person of summary, statistical, or aggregate information that does not identify individual cancer patients.

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Date

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