

4606.3307 AUTHORIZED RESEARCH.

Subpart 1. **Criteria.** The commissioner of health may enter into contracts to conduct research, using data collected pursuant to parts 4606.3300 to 4606.3309, with public and private research agencies or with individuals who satisfy all of the following criteria:

A. the research proposed to be conducted will assist in improving the diagnosis, treatment, or prevention of cancer and the public health;

B. there is documented evidence that the principal investigator for the research proposed is qualified:

(1) by having attained the degree of medical doctor, doctor of dental surgery, doctor of science, doctor of philosophy, or equivalent degree from an accredited college or university; and

(2) by specific academic graduate level training in epidemiology, biomedical research or biometry, or documented evidence of biomedical or related medical research experience; and

C. there is a written protocol which includes but is not limited to a complete description of:

(1) the proposed scientific research hypotheses;

(2) the purpose of the proposed research;

(3) the specific methodologies, including data required from the commissioner, to be used in conducting the research and testing of scientific hypotheses;

(4) the projected or anticipated result of the research;

(5) the period of time during which the proposed research will be conducted and when a final report will be completed;

(6) the physical facilities to be employed in conducting the research; and

(7) the methods to be used to assure that privacy of data is maintained in accordance with state law, and that access to private, nonpublic data is limited to those authorized by the commissioner to have access.

Subp. 2. **Release of information.** Under no circumstances will researchers be provided access to personal identifiers that would allow contact of a patient without attempting to obtain physician consent as described in part 4606.3306. The following personal identifiers will not be released:

A. last name;

B. first name;

C. middle name or initial;

- D. address;
- E. county of residence; or
- F. social security number.

No researcher operating under contractual agreement with the commissioner as described in subpart 1 shall release any personal identifier, mark, or description obtained during an investigation that could be used for identification of an institution, a physician, or an individual who is or was the subject of a case report required in part 4606.3303.

Subp. 3. **Evaluation of proposals.** The commissioner shall evaluate proposals based upon the criteria in items A to E.

A. The proposed research has social and scientific merit that is directed primarily toward improving the diagnosis, treatment, defining of risks, or prevention of cancer.

B. All coinvestigators are qualified to undertake the proposed research by means of specific academic training or demonstrable, related experience in epidemiology, medical, biomedical, or statistical research.

C. The hypotheses to be tested are explicit, and are determined to be researchable and feasible by the scientific peer review committee described in subpart 4.

D. The methods proposed for testing the hypothesis clearly define:

- (1) the population or cancers to be studied;
- (2) the type and amount of data to be collected;
- (3) the source of the data;
- (4) the procedures for collecting and maintaining the data; and
- (5) the specific measurement techniques to be employed in analysis of data, including discussion of: major variables, statistical methods, methods of testing data reliability and validity, and required levels of accuracy, precision, or completeness of the data to be collected.

E. The results of this study will be interpreted so that the findings can be used or generalized to other populations and provide a timely, substantive, and important contribution to the understanding of cancer diagnosis, treatment, or prevention in Minnesota.

Subp. 4. **Scientific peer review committee.** To assist in evaluating the scientific merits of proposals for research, the commissioner may appoint up to seven scientists to conduct scientific peer review who are qualified by having:

A. attained the degree of medical doctor, doctor of science, doctor of philosophy, or equivalent degree from an accredited college or university;

B. specific training in medicine, epidemiology, cancer research, or biometry from an accredited college or university; and

C. two or more years of applied experience in epidemiology, medical research, biomedical research, or biometry.

Statutory Authority: *MS s 144.05; 144.671 to 144.69*

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