GUIDELINES FOR REVIEWING REQUESTS FOR INFORMATION FROM THE CANCER REGISTRY DATA BASE

INTRODUCTION

Each request for information shall be in writing and shall state specifically what data are being requested (time period, geographic area, ICDO sites, etc.). Any request that does not contain sufficient detail to permit an evaluation of the desired information by the Cancer Registry Program staff with a reasonable expenditure of time and effort may be rejected by the Cancer Registry Subcommittee of the Cancer Prevention and Control Advisory Committee. Requests for information from the Cancer Registry data base will be classified according to whether or not patient identifying information is being sought. Those requests that do no not seek personal identifying variables (Summary Data Requests) will be evaluated to determine that patients will not be indirectly identified. Data requests calling for patient identifying information (patient names, doctor names, etc.) will be evaluated to assure that appropriate procedures will be followed by the investigators. Guidelines for reviewing both types of requests are provided. Also, investigators will probably be asked to pay the cost of retrieving the requested information.

SUMMARY DATA REQUEST GUIDELINES

Cancer patient data summary tabulations not provided in the Cancer Registry Annual Report will be released after the request has been reviewed in accordance with the following guidelines:

A. No data that directly or indirectly identifies cancer patients shall be provided. Physician codes shall be released only in a form that cannot be used to identify patients, although it may permit distinctions to be made among unidentifiable individuals.

B. Data will be considered to have a reasonable possibility of indirectly identifying cancer patients if it includes tabulations of any of the following information:

    1. Physician or hospital identification code in combination;
    2. Date of birth, unless converted to age in years;
    3. Diagnosis date unless converted to week, month, or year.
    4. Rates, tabulations, or frequencies that are based on five or fewer cases for any one site of cancer.

C. The number of cancer cases for any type of cancer by town for the time interval being summarized will only be provided by the following demographic grouping variables (gender, age-group, race, etc.).

Information that meets the Summary Data Request Guidelines and contains none of the combinations of data described will be released.

The Cancer Registry Subcommittee will review for approval requests from outside of the Department of Human Services for release of rates, tabulations, or frequencies based on five or fewer cases.

INDIVIDUAL DATA REQUEST GUIDELINES

The following information must be submitted prior to the review of individual patient identifying information requests by the Cancer Registry Subcommittee of the Cancer Prevention and Control Advisory Committee:

A. A comprehensive protocol which contains a satisfactory study description; i.e., the investigator's qualifications and affiliation, study background, research question, research design, case definition and selection, control definition and selection, informed consent and confidentiality, study resources, study operational description, and data analyses.

B. A statement which identifies the resulting benefits of the study for Maine residents.

C. The submission of an Institutional Review Board (IRB) approval for this study by an IRB formed in accordance with the provisions of U.S. Department of Health and Human Services Code of Federal regulations or Protection of Human Subjects (45 CRF 46, revised March 8, 1983).

Investigators should be advised that supplying the above information does not automatically insure their access to the requested data but only that their request will be given appropriate consideration by the Cancer Prevention and Control Advisory Committee. The committee may elect to impose specific conditions or routine reporting requirements on investigators gaining access to individual identifying information from the Cancer Registry data base in order to insure that their study is being conducted in an appropriate manner.

Investigators should also be advised that the Committee may ask very detailed questions about the provision of assurances involving the release of the information to subcontractors, the security of data storage facilities, how informed consent will be obtained from cancer patients, and the committee may want a general statement of the ethical principles the investigators will follow.

EMERGENCY EXCEPTIONS

The committee recognizes the remote possibility that an emergency situation could arise in which it is necessary to contact cancer patients and/or their physician without prior committee approval. In such a situation, Cancer Protection and Control Advisory Committee members will be advised of the problem, and a committee meeting convened as soon as possible. All patient contacts, if they are made, will be with the prior approval of the patient's physician and they will be made by the Department of Human Services Personnel.