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CH. 24 GUAM RESEARCH REVIEW BOARD

CHAPTER 24
GUAM RESEARCH REVIEW BOARD

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§ 24101. Definitions.

As used in this Chapter:

- (a) *Board* means the Guam Research Review Board.
- (b) *Investigator* means any individual, public or private entity, or agency engaged in or purposing to engage in research subject to regulation.
- (c) *Legally* authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.
- (d) *Research* as defined in the Federal Register, §102 Definitions.
- (e) *Research* subject to regulation means research involving human subjects.
- (f) *Human subjects* means a living individual about whom an investigator conducting research obtains:
 - (1) Data Through Intervention or Interaction with the Individual. Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

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(2) Identifiable Private Information. Private information may include information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will *not* be made public (for example, medical records). Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects.

(g) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

§ 24102. Board; Terms; Appointment; Continuance; Removal.

Members of the Board shall be consistent with the University of Guam's Committee on Human Subjects and Research which is: three (3) or four (4) professional research proficient experts from the University of Guam; at least one (1) Guam community representative; at least one (1) local religious leader; and at least one (1) licensed practicing local medical doctor.

§ 24103. Purpose.

The purpose of the Board is to review, approve, require modifications to secure approval or disapprove all research subject to regulation.

§ 24104. Powers.

The Board shall have and exercise each and all of the following powers:

(a) review and have authority to approve, require modifications to secure approval or disapprove all research activities covered by the rules and regulations;

(b) require documentation of informed consent of all human subjects participating in the research subject to regulation. At the Board's discretion, require additional information be given to the subjects which would add to the protection of the rights and welfare of the subjects;

(c) notify the investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure approval of the research activity. If the Board decides to

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disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing;

(d) conduct continuing review of research subject to regulation at intervals appropriate to the degree of risk, but not less than once per year and shall have authority to observe or have a third party observe and consent to the process and the research; *and*

(e) to disapprove research subject to regulation which had been previously approved.

§ 24105. Duties of Investigators.

The proposals, plans, procedures and protocols for all proposed research subject to regulation shall be submitted to the Board for review, approval, modification or disapproval. No research subject to regulation shall be conducted without Board approval. The plans, procedures and protocols for all research subject to regulation which is being conducted at the time of the enactment of this legislation shall be submitted to the Board for review, approval, modification or disapproval within thirty (30) days of this bill becoming law. Research subject to regulation which is being conducted at the time of the enactment of this legislation may continue pending Board action.

§ 24106. General Requirements for Informed Consent.

No investigator may involve a human being in research subject to regulation *unless* the investigator has obtained the legally effective informed consent of the subject, or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate, and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. Unless otherwise provided by law or regulation, no informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the research sponsor, if different, or their agents from liability for negligence.

(a) Basic Elements of Informed Consent. Except as provided in Paragraphs (c) or (d) of this Section, in seeking informed consent the

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following information shall be provided to each human subject or the subject's legally authorized representative:

(1) a statement that the study involves research, an explanation of the purpose of the research and the expected duration of the subject's participation, description of the procedures to be followed and identification of any procedures which are experimental;

(2) a description of any reasonably foreseeable risk or discomforts to the subject;

(3) a description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) a disclosure of appropriate alternative procedures or courses or treatment, if any, that might be advantageous to the subject;

(5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs, and, if so, what it consists of or whether further information may be obtained;

(7) an explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject; *and*

(8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional Elements of Informed Consent. When appropriate, the Board may require that one (1) or more of the following elements of information shall also be provided to each subject:

(1) a statement that the particular treatment or procedure may involve risks to the subject, or to the embryo or fetus, if the subject is or may become pregnant, which are currently unforeseeable;

(2) anticipated circumstances under which the subject's participation may be terminated by an investigator without regard to the subject's consent;

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(3) any additional cost to the subject that may result from participation in the research;

(4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; *and*

(6) the approximate number of subjects involved in the study.

(c) The Board may approve a consent procedure which does *not* include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent; provided, that the Board finds and documents that:

(1) the research or demonstration project is to be conducted by, or subject to, the approval of Federal, state, territorial or local government officials, and is designed to study, evaluate or otherwise examine: (i) public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes and/or alternatives to those programs or procedures; *or* (iv) possible changes in methods or levels of payments for benefits or services under those programs; *and*

(2) the research could *not* practically be carried out without the waiver or alteration.

(d) The Board may approve a consent procedure which does *not* include, or which alters, some or all of the elements of informed consent set forth in this Section, or waives the requirements to obtain informed consent; provided, that the Board finds and documents that:

(1) the research involves no more than minimal risk to the subject;

(2) the waiver or alteration will *not* adversely affect the rights and welfare of the subject;

(3) the research could *not* practically be carried out without the waiver or alteration; *and*

(4) whenever appropriate, the subjects will be provided with additional and pertinent information after participation.

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(e) The informed consent requirements are *not* intended to preempt any applicable Federal, state or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this Section is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or territorial law.

§ 24107. Criteria for Board Approval of Research.

In order to approve research subject to regulation, the Board shall determine that all the following requirements are satisfied:

(a) Risks to subject are minimized: (i) by using procedures which are consistent with sound research design and which do *not* unnecessarily expose subject's to risk; and (ii) whenever appropriate by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(b) Risks to subject are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the Board should consider only those risks and benefits that may result from the research, as distinguished from risks and benefits of therapies subject would receive even if *not* participating in the research. The Board should *not* consider possible long range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(c) Selection of the subjects is equitable. In making this assessment the Board should take into account the purposes of the research and the setting in which the research would be conducted and should be particularly cognizant of the special problems that research involving vulnerable populations, such as children, prisoners, pregnant woman, persons with disabilities, the elderly, or economically or educationally disadvantaged persons.

(d) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Board regulation.

(e) Informed consent will be appropriately documented, in accordance with, and to the extent required by Board regulation.

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(f) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(g) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, the elderly, prisoners, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons, additional safeguards have been included in the research plans, procedures or protocols to protect the rights and welfare of these subjects.

(h) Progress reports or thesis shall be made available to subjects participating in the research as appropriate.

§ 24108. Grievance Procedure.

If application for approval is denied for a research proposal, investigators may appeal to the Dean of the Graduate School and Research. The Dean will appoint an ad hoc committee for a second, independent review of the research project. The findings of the ad hoc committee are to be presented to the Committee on Human Subjects in Research no later than ninety (90) days after receipt of grievance from the investigator, to determine the final decision to approve or not to approve a research project.

§ 24109. Fines and Penalties.

Upon determination of the Review Board through the approved rules and regulations, any investigator, research sponsor or their agents, which conducts research subject to regulation in violation of this Chapter shall be subject to a fine of One Thousand Dollars (\$1,000.00) per each violation, and shall be prohibited from continuing and conducting human research studies for not less than two (2) years.

The Dean of the Graduate School and Research shall refer any cases determined by the Review Board as a valid violation to the Attorney General's Office for investigation and prosecution.

§ 24110. Appropriation: Authorization.

There is hereby appropriated from the General Fund a total of Forty Thousand Dollars (\$40,000.00) for the purpose of hiring one (1) clerical staff and other accommodations necessary to assist with the function of

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processing applications. This appropriation shall continue until expended for the operations and purposes specified herein.
