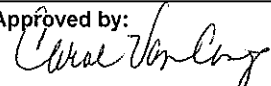


 HAWAII HEALTH SYSTEMS C O R P O R A T I O N POLICY	<i>Quality Through Compliance</i>	Policy No.: RES 001A
		Revision No.: 2
Subject: <i>Corporate Institutional Review Board Policy</i>	Issued by: Corporate Compliance	Effective Date: August 16, 2012
	Approved by:  HHSC Board of Directors By: Carol VanCamp Its: Secretary/Treasurer	Supersedes Policy: September 12, 2000 Page: 1 of 2

Implemented: August 16, 2012. Next Review: August 16, 2015

- I. **PURPOSE:** To ensure that research involving human subjects in HHSC facilities is done in an ethical manner which protects the rights and welfare of human subjects.
- II. **POLICY:** Hawaii Health Systems Corporation ("HHSC") hereby gives assurance that it will comply with the Department of Health and Human Services ("DHHS") regulations for the protection of human research subjects (45 CFR Part 46) as specified below. HHSC may elect not to allow research involving human subjects in its facilities. Whenever such research is conducted, however, this policy shall be followed. In the event there are changes to the legal requirements applicable to this activity, these policies shall be construed in a manner that is consistent with the law.

It is HHSC policy that:

- A. Research investigators bear full responsibility for the performance of all research covered by this policy, including full responsibility for complying with federal, State, and local laws as they may relate to such research.
- B. HHSC assures that before humans are involved in research, proper consideration will be given to the following:
 1. Risks to the subjects;
 2. Anticipated benefits to the subjects and others;
 3. Importance of the knowledge that may reasonably be expected to result;
 4. Informed consent process to be employed;
 5. Provisions to protect the privacy of subjects; and
 6. Additional safeguards for vulnerable populations.
- C. HHSC recognizes the need for appropriate additional safeguards in research involving human subjects who are likely to be vulnerable to coercion or undue influence, such as children, pregnant women, mentally disabled persons, educationally or economically disadvantaged persons or fetuses.
- D. HHSC encourages and promotes constructive communication among the facility administrators/Regional CEOs, facility research administrators (where applicable),

department heads, research investigators, clinical care staff, human subjects, and all other relevant parties as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

- E. HHSC will exercise appropriate administrative overview of implementation of these policies to assure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.

III. ETHICAL PRINCIPLES GOVERNING RESEARCH INVOLVING HUMAN SUBJECTS:

HHSC is guided by the ethical principles regarding all research involving humans as subjects as set forth in the 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report") and as specified below:

HHSC recognizes the principles of respect for persons, beneficence (including minimization of harms and maximization of benefits), and justice as stated in the Belmont Report and will apply these principles in all research covered by this policy.

HHSC acknowledges and accepts its responsibilities for protecting the rights and welfare of human research subjects.

- IV. RESEARCH REVIEW and HUMAN SUBJECTS USE APPROVAL:** HHSC shall either constitute an Institutional Research Board ("IRB") or enter into an agreement with an established IRB. The IRB shall be used by all HHSC facilities and the procedures as agreed upon in any agreement with an established IRB shall be followed. Each HHSC facility shall have a procedure to review and approve any research requests involving human subjects before submitting for IRB review. If necessary, a Corporate Research Implementation Committee (RIC) may be established by the HHSC President and CEO.

- V. APPLICABILITY:** Except for research exempted under the DHHS regulations 45 CFR 46.101(b), this policy applies to all research involving human subjects, and all other activities which, even in part, involve such research, regardless of whether the research is otherwise subject to federal regulation, if:

- A. The research is conducted by or under the direction of any employee, member of the medical staff, or agent of this institution using any property of an HHSC facility in connection with institutional responsibilities, or;
- B. The research involves the use of HHSC nonpublic information to identify or contact human research subjects or prospective subjects.

Any patients under the supervision or control of law enforcement within HHSC facilities may not be subjects of the experiment.

This policy shall apply to all HHSC facilities, employees, volunteers, and medical staff members.

- VI. AUTHORITIES:** 45 CFR Part 46.