HAWAII HEALTH SYSTEMS CORPORATION "Touching Lives Everyday" Policies and Procedures	*Quality Through Compliance*	Policy No.: **RES 0001**
		Revision No.: 1
	Issued by: Corporate Legal Department	Effective Date: November 14, 2002
Subject: ***Quality: Corporate Institutional Review Board Policy***	Approved by: HHSC Board of Directors By: Jean Odo Its: Secretary/Treasurer	Supersedes Policy: September 12, 2000
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I. PURPOSE: The purpose of this policy is to ensure that any research involving human subjects is done in an ethical manner which protects the rights and welfare of human subjects.

II. POLICY: Hawaii Health Care System ("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 46) as specified below. HHSC may elect to not allow research involving human subjects. 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.

III. ETHICAL PRINCIPLES AND INSTITUTIONAL POLICIES GOVERNING RESEARCH INVOLVING HUMAN SUBJECTS:

A. Applicability:

1. 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, <u>or</u>
   b. The research involves the use of HHSC nonpublic information to identify or contact human research subjects or prospective subjects.

2. Prisoners may not be subjects of the experiment.

3. HHSC does not participate in basic research.

B. Ethical Principles Governing Human Research Subjects Research: 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.

1. 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.

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

C. Policies:

1. 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.

2. HHSC assures that before humans are involved in research, proper consideration will be given to:

   a. The risks to the subjects,
   b. The anticipated benefits to the subjects and others,
   c. The importance of the knowledge that may reasonably be expected to result,
   d. The informed consent process to be employed,
   e. The provisions to protect the privacy of subjects, and
   f. The additional safeguards for vulnerable populations.

3. 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.

4. HHSC encourages and promotes constructive communication among the facility administrators/Regional CEOs, research administrators, 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.

5. 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.

IV. INSTITUTIONAL REVIEW BOARD, FACILITY ADMINISTRATOR AND INVESTIGATOR COMPLIANCE WITH 45 CFR 46:

A. Facility Administrator Responsibilities:

1. If any physician or principal investigator(PI) is interested in conducting research they must contact Hawaii Pacific Health (HPH)to request the research application

packet, since HPH will be the Institutional Review Board (IRB) of record for HHSC research projects.

2. The PI will then submit the completed research application packet to the facility Medical Director or the Facility Administrator. The facility Medical Director or facility Administrator will send the completed research application packet on human subjects to the Corporate Director of Quality Assurance and Corporate Compliance.

3. The Corporate Director of Quality Assurance and Corporate Compliance will maintain a file, which will include a copy of the protocol, a copy of the HPH IRB approval/denial letter, and any communications regarding the research project.

4. The HPH IRB will be the IRB of record and will fulfill the duties of an IRB as specified in 45 CFR. The Corporate Director of Quality Assurance and Corporate Compliance will make a report by December 1 of each year to the Board of Directors via the Quality Improvement and Assurance Committee concerning the nature of any research conducted in the past year and results of pertinent HPH IRB reviews.

B. HHSC Research Implementation Committee (RIC) Composition:

1. The HHSC Research Implementation Committee (RIC) shall have at least 10 members with varying backgrounds and sufficiently qualified through expertise and experience to promote respect for its advice and counsel in the acceptability and desirability of new research projects at HHSC. The Regional CEOs will choose one member from each of the regions and the HHSC Board of Directors will approve them. The President and CEO of HHSC will choose the other five members and they will also be approved by the HHSC Board of Directors. A minimum of five committee members is needed to discuss and approve a research project.

2. The RIC shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas .

3. The RIC shall include at least one member who is not personally or through family ties affiliated with the facility involved in the research.

4. No RIC member may participate in review of a project in which the member has a conflicting interest, except to provide information requested by the RIC.

C. RIC Responsibilities:

1. The HHSC RIC, which hereafter will be known as the “RIC”, shall review, and have the authority to approve, require modification in, or disapprove a research activity or proposed changes in it before human subjects may be involved. The reviews shall be conducted at convened meetings where a majority of the members are present. Approval requires a vote of the majority present except where expedited review is allowed.

2. The RIC shall notify HPH that they have approved a research protocol. The HPH liaison will take the research protocol to the HPH IRB for approval or denial. The HPH IRB will notify the principal investigator and the facility administrator in writing of its decision to approve or disapprove the proposed research activity, or of

modifications required to secure approval. Written notification shall be given to the investigator. The investigator shall be given the right to respond in writing.

3. The RIC shall adopt written policies and procedures as necessary.