	DEPARTMENT OF PUBLIC SAFETY	EFFECTIVE DATE: MAR 0 9 2010	POLICY NO.: COR.10.1I.06
	CORRECTIONS ADMINISTRATION POLICY AND PROCEDURES	SUPERSEDES (Policy No. & Date): COR.10.1I.06 (12/29/08)	
	SUBJECT: MEDICAL RESEARCH		Page 1 of 5

1.0 PURPOSE

This purpose of this policy is to ensure that inmates' participation in medical research meets all ethical, legal and medical guidelines for participation by human subjects.

2.0 REFERENCE AND DEFINITIONS

.1 References

a. Hawaii Revised Statutes; Section 26-14.6, Department of Public Safety; and Section 353C-2, Director of Public Safety, Powers and Duties.

b. National Commission on Correctional Health Care. Standards for Prisons and Jails, (2008).

.2 Definitions

a. Limited Data Set - Refers to protected health information (PHI) that excludes categories of direct identifiers and may be used or disclosed for purposes of research, public health or health care operations without obtaining either an individual's authorization or waiver for its use and disclosure.

b. Limited Data Use Agreement - An agreement that the researcher and the Department enters into that establishes the ways in which the information gather during the research may be used and disclosed.

c. Human Subjects Research - **Human subject research** includes experiments (formally known as interventional studies) and observational studies. This includes any human subjects that are participants in research on basic biology, clinical medicine, psychology, and all other social sciences. Human subjects research does not include data and information gathered or transmitted for the purposes of internal clinical/medical decision making, program

3.0 POLICY

.1 The Department of Public Safety does not conduct research activities.

.2 Inmates shall not participate in clinical research trials unless all ethical, legal and medical standards are met, the protocol has been authorized by an external Institutional Review Board (IRB), approval is granted by the Director of Public Safety, the research subjects have full disclosure and the research subjects have signed a written authorization to participate in the research.

.3 There shall be no cosmetic or drug trials or tests of substances on inmates to determine ill effects or side effects prior to sale to the general public.

.4 A researcher may conduct limited data research upon securing the approval from an external IRB and with authorization from the inmate. Approval from the Director of Public Safety also is required.

4.0 PROCEDURES

.1 Collection of statistical or epidemiological data on inmate health and health care operations are permitted if required by law or policy. Such data collection shall ensure anonymity except as required by law and shall be held in confidence.

.2 A limited data set de-identifies all elements that could be used to identify an individual who is the subject of the information or the individual's relatives, employers, or household members alone or in combination with other information. Under this method the identifiers that must be removed are the following:

a. Name.

b. Individual birth dates, admission dates, housing assignments, discharge dates, date of deaths except if the data is aggregated into a single category and not individualized.

c. Social security numbers.

d. Medical record numbers.

e. Account/fiscal/financial numbers.

f. Employment/personnel numbers.

g. Certificate/licenses/serial or prison numbers.

h. Device or Biometric identifiers, including fingerprints and voiceprints.

i. Full-face or profile photographic images and any comparable images.

j. Any other unique identifying number, characteristic, or code that could be traced to an individual; including SID #'s and any and all Criminal Case #'s.

.3 A limited data use agreement is the means by which the Department obtains satisfactory assurances from the researcher that the use and disclosure of the research data is for specific purposes. A written data use agreement is required even if the person requesting a limited data set for research purposes is an employee or otherwise a member of the Department's workforce.

.4 A data use agreement shall contain the following provisions:

a. Specific permitted uses and disclosures of the data by the recipient consistent with the purpose for which it was gathered.

b. Identify who is permitted to use or receive the limited data set.

c. Stipulations that the recipient will not use or disclose the information other than what is permitted by the agreement or otherwise required by law.

d. Stipulations that the recipient will use appropriate safeguards to prevent the use or disclosure of the information except as provided for in the agreement and shall require the recipient to report to the Department any uses or disclosures in violation of the agreement of which the recipient becomes aware.

e. Stipulations that the recipient will hold any agent of the recipient (including subcontractors) to the standards, restrictions and conditions stated in the limited data use agreement with respect to the information.

f. Stipulations that the recipient will not make any attempt to identify the individuals or contact the individual subjects.

g. The limited data use agreement shall forbid the recipient from further disclosure of the authorized information, except as stipulated in the agreement, without written authorization by the Director of Public Safety.

h. The recipient shall not disclose the information in a way that would violate Protected Health Information (PHI) privacy rules.

.5 Research that will identify the subject requires that the subject authorize the disclosure of his or her PHI for research purposes. Before the subject authorizes the use of his or her PHI, the researcher is required to give the subject a full disclose of the research, how the PHI will be used and disclosed, for how long and for what purpose, and any consequences associated with the disclosure if any exist and are known by the researcher.

.6 The informed consent shall be sought from and documented for each prospective subject or the subject's legally authorized representative in accordance with, and to the extent required by state and federal law.

.7 The external IRB shall be the responsible for ensuring that all research conforms with applicable standards. All affirmative review results are subject to approval by the Director of Public Safety before inmates are entered as subjects in a research project.

.8 All persons undertaking medical research shall meet with the staff of the Department's Office of Research and Statistics for a briefing about confidentiality and applicable laws and regulations and to sign a Research Agreement.

5.0 SCOPE

This policy and procedure applies to all correctional facilities and their assigned personnel.

APPROVAL RECOMMENDED:

3/8/10
Medical Director Date

3/8/10
Corrections Health Care Administrator Date

3/9/10
Deputy Director for Corrections Date

APPROVED:

Director

3/9/10
Date