1.0 PURPOSE

The purpose of this policy is to ensure that biomedical, behavioral, or other research using incarcerated individuals as subjects is consistent with established ethical, medical, legal, and regulatory standards for human research.

2.0 SCOPE

This policy and procedure shall apply to all correctional facilities, their assigned personnel, contract staff, and others requesting to conduct research.

3.0 REFERENCES, DEFINITIONS & FORMS

.1 References

a. 21 CFR 50, Protection of Human Subjects (2022).

b. 21 CFR 56, Institutional Review Boards (2022).

c. 45 CFR 46 (2018 Common Rule), Protection of Human Subjects (2018).

d. Code of Federal Regulations Title 21, 45 CFR 160-169, Federal Register Documents, (2023).

e. Hawaii Revised Statutes §323B, Health Care Privacy Harmonization Act.

f. Hawaii Revised Statutes §324, Medical Research; Morbidity and Mortality Information.

g. Position Statement: Health Services Research in Correctional Settings, National Commission on Correctional Health Care, (2020).

h. Standards for Health Services in Prisons. National Commission on Correctional Health Care, (2018).

i. Standards for Health Services in Jails. National Commission on Correctional Health Care, (2018).

j. Standards for Mental Health Services in Correctional Facilities. National Commission on Correctional Health Care, (2015).

k. Performance-based Standards and Expected Practices for Adult Correctional Institutions. The American Correctional Association. Standards: 5-ACI-1F-13, 5-ACI-1F-14, 5-ACI-1F-15, 5-ACI-1F-16, 5-ACI-1F-17, 5-ACI-1F-18, 5-ACI-6C-09, (2021).

.2 Definitions:

a. Data Use Agreement: A written agreement by the principal investigator and the Department of Public Safety that establishes the ways in which the information gathered during the research will be safeguarded, used, stored, and disclosed in accordance with state and federal laws.

b. Confidentiality: As human subjects of research, incarcerated individuals, employees, and contracted staff have a right to expect that non-public information gathered about them for a particular study will not be divulged in a manner that identifies any individual and/or specific facts about that individual. The expectation of confidentiality applies not only to the procedures by which the research is carried out and to the published findings of the research, but also to non-research related communications of the researcher.

c. Limited Data Set: Protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

1. Names.

2. Housing assignment or postal address information, other than town or city, State, and zip code.

3. Telephone numbers, fax numbers, and electronic mail addresses.

4. Social security numbers.

5. Medical record, prisoner identification, and criminal case numbers.

6. Birth dates, admission dates, discharge dates, dates of death except if the data is aggregated into a single category and not individualized.

7. Health plan beneficiary numbers.

8. Account, fiscal, and financial numbers.

9. Certificate and license numbers.

10. Employment and personnel numbers.

11. Vehicle identifiers and serial numbers, including license plate numbers.

12. Device identifiers and serial numbers, Web Universal Resource Locators (URLs), and Internet Protocol (IP) address numbers.

13. Biometric identifiers, including finger and voice prints.

14. Full face photographic images and any comparable images.

15. Any other unique identifying number, characteristic, or code that could be traced to an individual.

d. Research: The careful and systematic study and investigation of a field of knowledge which is undertaken to discover or establish facts or principles, to determine the impact and/or effectiveness of practices, or to study the possible impact of change on a system.

e. Human Subjects Research Review Committee: A multi-disciplinary team, appointed by the Director, or their designee, created to review research studies to determine compliance with guidelines dealing with the use of human subjects in research and with professional research standards.

.3 Forms:

a. Application for Review of Research Proposal.

4.0 POLICY

.1 The department supports, encourages, uses, and engages in research activities beneficial and relevant to its correctional programs, services, and operations.

.2 The department shall govern the conduct of research within the agency, including compliance with professional and scientific ethics and with state and federal guidelines.

5.0 PROCEDURES

.1 Research Proposals

a. All external and internal projects defined as research must be reviewed and approved by the Human Subjects Research Review Committee (HSRRC).

b. Research activities conducted by departmental employees, as directed by the division administrator or designee, for the purpose of clinical and medical decision-making, quality assurance, continuous quality improvement, fiscal management, accreditation, audit, and other operational health care activities do not need the HSRRC review or approval, unless the research is also being used for a student project (e.g., course paper, master's thesis, doctoral dissertation).

c. Any research project conducted using information collected directly from incarcerated individuals or employees, or obtained from the department concerning incarcerated individuals, others under the jurisdiction of the department, or employees of the department, must adhere to generally accepted standards of confidentiality of subjects' identities.

d. An Application for Review of Research Proposal shall be submitted to the HSRRC for all proposed research.

e. The HSRRC review of research proposals shall include, but not be limited to, the following standards:

1. If the research involves the use of incarcerated individuals under the jurisdiction of the department as human subjects, the application must demonstrate a clear and reasonable nexus for using an incarcerated population.

2. If the research involves the use of incarcerated individuals, or information about incarcerated individuals, the application must meet appropriate standards for privacy, confidentiality, and the protection of the welfare of the incarcerated individuals. For a research proposal to garner HSRRC approval, the proposal must address protection of

privacy, confidentiality of subjects, and must also include a clear data security plan.

3. Projects that pose a significant physical or mental health risk to incarcerated individuals will not be approved.

4. Research projects which involve the use of incarcerated individuals or departmental employees as human subjects, or require information about incarcerated individuals or departmental employees, cannot be conducted by current or former incarcerated individuals.

5. Compensation, remuneration, or payment of any kind to incarcerated individuals, or their relatives or friends, for the incarcerated individual's participation in research projects is not permitted. Additionally, compensation, remuneration, or payment to employees for participation in research projects is not permitted.

6. The cost of the project to the department, if any, shall be considered in the decision to approve or disapprove the research application.

7. When incarcerated individuals who are participants in a community-based research protocol are admitted to a facility operated by the department, research applications provide for:

   a) Continuation of participation, as approved by the Medical Director or designee; or

   b) Consultation with community researchers by the Medical Director or designee so that withdrawal from the research protocol is done without harming the health of the incarcerated individual.

8. Participation in research must be voluntary and participants must be informed regarding risk of harm, possible benefits, and other details of the proposed study. Written informed consent from potential subjects prior to research participation must be obtained, when indicated.

9. Projects must be approved by an independent Institutional Review Board (IRB) with a prisoner representative in which the department has an existing written agreement documenting the department's reliance on the IRB for oversight of the research, and the responsibilities of each entity prior to final approval by the HSRRC. If

the IRB needs approval from the department prior to providing their own approval, the HSRRC may provide tentative approval.

10. Projects conducted by faculty, students, or others with an academic affiliation must also be approved by the appropriate college or university Institutional Review Board (IRB) prior to final approval by the HSRRC. If the IRB needs approval from the department prior to providing their own approval, the HSRRC may provide tentative approval.

11. Project personnel are expected to have study-specific qualifications; that is, there is a presumption that project personnel have the substantive and methodological knowledge to successfully complete the proposed study. Student-led projects must be supervised by an advisor with appropriate credentials to conduct the research.

12. Individuals completing research related to internships at the department shall submit research proposals to the HSRRC.

13. Current and former employees of the department may propose research involving incarcerated individuals or employees as subjects in research studies, as part of an educational training program or degree program, provided the following conditions are met:

    a) The current or former employee is in good standing with the department at the time the research proposal is received by the HSRRC.

    b) A current employee of the department must agree to complete the research on their own personal time, and not while at, or engaged in duties for their institution of employment.

    c) Current and former employees are encouraged to conduct the research at an institution other than the current or most recent institution of employment. Exceptions may be granted with the approval of the HSRRC.

    d) Current and former employees will not be granted any greater access to, or privileges from department institutions at which they are conducting research, relative to any outside researcher conducting a study utilizing one or more institutions.

14. A research proposal that is not approved may be returned to the researcher. A research proposal that is rejected by the HSRRC cannot be resubmitted.

f. The applicant may request an endorsement letter from the department to meet requirements from a funding source or an IRB. However, the research proposal shall undergo a full review and must receive all necessary approvals before the applicant is authorized to conduct the research study.

.2 Proscription of Research

a. Prohibited experimental programs include but are not limited to aversive conditioning, psychosurgery, or cosmetic substances being tested prior to sale to the general public.

b. Participation of incarcerated individuals in medical or pharmaceutical research purely for experimental purposes is not permitted.

c. In rare and exigent circumstances, the Medical Director may authorize use of an experimental treatment for an incarcerated individual on a case-by-case basis, utilizing appropriate institutional reporting and documentation of the case. An incarcerated individual's treatment with a new medical procedure by their provider should be undertaken only after the incarcerated individual has received a full explanation of the positive and negative features of the treatment, and only with informed consent.

.3 Data Use Agreement

Prior to conducting research, a fully executed written Data Use Agreement (DUA) shall be required between the principal investigator and the department. The DUA shall include, but not be limited to, the following provisions:

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

b. Identify who is permitted to use or receive data.

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

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

e. Stipulations that the researcher will hold any agent of the researcher (including subcontractors) to the standards, restrictions, and conditions stated in the DUA with respect to the management of information.

f. Stipulations that the researcher will not make any attempt to identify the research subjects or contact the research subjects for purposes beyond those identified in the DUA.

g. The DUA shall forbid the researcher from further disclosure of the authorized information, except as stipulated in the agreement, without written authorization by the Director of the department.

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

.4 Letter of Agreement

Prior to conducting research, a fully executed written Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA) shall be required between the principal investigator and the department. The MOU or MOA sets forth the terms and conditions under which the project may proceed and shall include, but not be limited to, the following:

a. Conforming to departmental and facility policies.

b. Responsibilities of the researcher and departmental employees in planning and implementing the research.

c. Protection of human subjects.

d. Security of confidential data.

e. Reporting requirements.

.5 Conduct of Approved Research

a. The conduct of research shall include compliance with professional and scientific ethics; medical or other health care, legal, and regulatory standards for human subject research; and all state and federal guidelines for the use and dissemination of research findings. Research shall conform to 45 CFR 46, 21 CFR 50, 21 CFR 56, and all relevant state and federal laws concerning the protection of human subjects, when applicable.

b. The researcher shall obtain written informed consent from incarcerated individuals and/or staff who are scheduled to participate in the research.

c. The researcher shall explain the study, and its justification, to all potential subjects or legally authorized representatives.

   1. A written summary, in non-technical language, shall be prepared to facilitate the explanation and a copy shall be provided to each potential subject or legally authorized representative.

   2. The researcher shall clearly explain to all potential incarcerated research subjects, or legally authorized representatives, that their participation in the research shall be purely voluntary, and that their participation shall, in no way, affect the term or length of their incarceration or supervision.

d. The principal investigator shall maintain adequate and securely stored records to enable the HSRRC or designee to ascertain the status of the study at any time.

e. Confidentiality shall be maintained throughout the course of all research activities in accordance with department policies and state and federal laws.

f. The privacy of research participants and their protected health information shall be maintained during all research activities.

   1. All documents, data compilations, reports, computer programs, photographs, and any other work provided to or produced in the course of research activities shall be kept confidential by the researcher unless written permission is granted by the Director for its release.

   2. All research data collected shall be stored by the researcher and by the facility in locked files with files located in a secured area.

g. Access to research data collected identifying incarcerated individuals and staff shall be limited to the researchers, HSRRC, and the appropriate division administrator or designee, as well as permitted health care staff when specified in the DUA for purposes of health care delivery to incarcerated individuals.

h. All research data and findings shall be reviewed for accuracy by the Director or designee prior to publication or dissemination.

i. All research data collected during the course of approved research shall only be used as specified in the Application for Review of Research Proposal, the DUA, and the MOU or MOA.

j. The Director or designee shall monitor the conduct of the research project to ensure compliance with approved departmental policies and agreements, as well as state and federal laws.

k. The cost of the project to the department (e.g., staff time required to pull files for review and monitor the project, escort incarcerated individuals, provide security for research personnel, computer support), shall be the responsibility of the researcher. When applicable, the department shall invoice the researcher with payment due upon receipt.

l. The research shall be conducted within a reasonable timeframe, as determined by the department.

m. The department reserves the right to terminate a project for any reason at any time during the course of the research.

.6 Reports on Research

a. Quarterly Status Reports: Once the project has been approved to begin, the principal investigator will be responsible for sending quarterly status reports to the Director or designee, the HSRRC, and the appropriate division administrator. The reports shall include a summary of the progress on data collection and analysis, a narrative describing the project activities, and any identified problems experienced during the reporting period.

b. Preliminary Findings Report: Immediately following the data collection and analysis phase of the project, the principal investigator shall submit a

summary report on the tentative findings of the study to the Director or designee, the HSRRC, and the appropriate division administrator.

c. Final Report: When the entire project is completed, and fourteen (14) days prior to the release of the report, the principal investigator shall submit the final report to the Director or designee, the HSRRC, and the appropriate division administrator.

.7 Use of Research Findings

a. As a general rule, research findings shall be published and distributed according to the research application, the DUA, and the MOU or MOA, regardless of the nature of the findings.

b. The Director or designee shall approve the distribution of all research.

c. A researcher cannot use data for any project other than the current project for which they have received the HSRRC approval and in accordance with the DUA and MOU or MOA.

d. In any report of results, researchers shall not use names of research subjects or describe any research subjects in such detail that they might be identified.

e. Researchers shall be required to ensure that records will be used solely in accordance with the DUA, the MOU or MOA, and in compliance with national, state, and federal guidelines to ensure that records are transferred in a form and manner that is not individually identifiable.

APPROVAL RECOMMENDED:

JAN 0 1 2024

Deputy Director for Corrections Date

APPROVED:

JAN 0 1 2024

DIRECTOR Date

STATE OF HAWAII
DEPARTMENT OF PUBLIC SAFETY
HEALTH CARE DIVISION

APPLICATION FOR REVIEW OF RESEARCH PROPOSAL

Pursuant to the State of Hawaii Department of Corrections and Rehabilitation Health Care Division policy COR 10.1I.06, both outside research proposals and internal research proposals must be reviewed and approved by the Human Subjects Research Review Committee (HSRRC) and recommended for approval to the Director, prior to the start of any research project. Eight (8) copies of the completed Application for Review of Research Proposal may be submitted to the *Human Subjects Research Review Committee, Department of Public Safety at 1177 Alakea St., 6th Floor, Honolulu, HI 96813.* The requirements for submitting research proposals are to include:

1. **Title of the Project**
2. **Principal Investigator:** To include name, address, telephone number, email address, and agency.
3. **Researchers:** Provide name(s), address, telephone number, email address, and affiliation of any researcher(s) or staff who may gain access to participants and/or data, including PHI.
4. **Funding source:** Describe originating funding source and any pass-through funding agencies.
5. **Study Facility:** To include the Hawaii jail or prison location(s) and/or affiliated administration office(s).
6. **Stakeholders & Institution Liaison:** Identify the stakeholders for this project, have you already contacted them? If yes, list who these individuals are.
7. **Project Abstract:** Briefly summarizes the purpose of the proposed research project (limit 250 words)
8. **Study Goals & Objectives**: Describes the goals and objectives of the proposed research project
9. **Justification for Project:**
    a. How will this research study expand the current knowledge base?
    b. If the study includes incarcerated individuals, please describe the rationale for using this vulnerable population, benefits to the department or program and the incarcerated population, and any additional safeguards to protect these participants.
10. **Participants:**
    a. Will the participants include incarcerated individuals, staff, or both?
    b. How will you identify these participants and then gain voluntary consent for your study (describe the criteria used)?
    c. How many participants anticipated to be included?
    d. Describe your study groups including any comparison groups and matching procedures for identification.
11. **Materials & Data Collection:**
    a. Are you gathering data that is not already routinely collected?
    b. Do you anticipate face-to-face interaction with these participants?

c. List all assessments or surveys that you plan to administer (attach as a copy) and describe the procedure proposed for administering these.

12. Electronic Data:

a. Do you intend to obtain existing electronic records? If yes, how do you plan to do so?
b. List the data elements you will be requesting for each of the following categories and provide justification for each of their collection:
    i. Personal information
    ii. Criminal justice records
    iii. Assessment data
    iv. Mental health treatment
    v. Medical records
    vi. Education records
    vii. Other

13. Data Analysis Plan: Describe the proposed data analysis plan for examining the research questions or hypotheses.

a. What statistical analysis will be conducted?
b. Will you be examining group differences and if yes, please describe?

14. Waiver of consent:

a. Why do you need data with identifying information (if applicable)?
b. If you are not obtaining participant consent or release forms, please describe why you don't require or why you are unable to gain authorization.

15. Institutional Review Board (IRB): Most research projects require protection of human subjects' rights, as provided by an IRB. If your project requires an IRB approval, submit a copy of the required IRB application(s), approval letter(s), and consent form(s) (please attach).

a. Has this project been submitted to an IRB: Y / N
b. If yes, has it been approved? Y / N / pending
c. If no, are there plans for an IRB review? Y / N
d. Attached (require all): Application / Approval / Consent form

16. Risks v. Benefits: Describe the study risks and benefits to participants. Keep in mind: is there more than a minimal risk to these participants? If yes, what are these and why pursue them?

17. Security Procedures

a. Describe procedures you will take to protect the privacy of participants' data.
b. How will you:
    i. Protect confidentiality of individuals who agree to participate?
    ii. Ensure physical security of the data?
    iii. Dispose of this data?

18. Impact on Institutional Operations and PSD HCD Resources: Describe the prospective impact of your study, specifically addressing security concerns, staff required to escort researchers into facilities, resources to provide electronic datasets, and other staff involvement with the project.

19. Timeframes: What are the key timeframes for your study (e.g., start/end of data collection, completion of study; suggest a timeline format).