RHODE ISLAND DEPARTMENT OF CORRECTIONS
POLICY AND PROCEDURE

	POLICY NUMBER: 6.06-4 DOC	EFFECTIVE DATE: 11/03/14	PAGE 1 OF 13
	SUPERCEDES: 6.06-3 DOC	DIRECTOR: Ashbel T. Wall II	Please use BLUE ink.
SECTION: INFORMATION SYSTEMS AND RESEARCH		SUBJECT: RESEARCH	

AUTHORITY: Rhode Island General Laws (RIGL) § 42-56-10 (22), Powers of the director

REFERENCES: ACA standard #'s 4-4108 (support of parent agency); 4-4109 (written p&p re: outside professionals); 4-4110 (assistance provided to researchers); 4-4111 (written p&p governing conduct of research); 4-4112 (approval prior to implementation); 4-4113 (written p&p re: voluntary inmate participation). Policy # 2.09-1 DOC, Accountability of Inmate Money/Checks; 2.20-4DOC, Fiscal Notes/Prison Impact Statements; 6.05-2 DOC, Program Evaluation; 9.18-4 DOC, Introduction of Unauthorized Items into the Adult Correctional Institutions; 9.23-2 DOC, Access to ACI Facilities by Staff and Persons Providing Services to RIDOC; 9.24-3 DOC, Entry to/Exit from Secure Facilities; Federal Regulations on Medical Research in Correctional Institutions, 45 CFR 46, Rev. 10/01/94 45 CFR Parts 160 and 164; NCCHC Standards J-69, Medical Research; P-72, Medical Research; DoIT Encryption Data User Agreement

INMATE / PUBLIC ACCESS?	X YES
AVAILABLE IN SPANISH?	X NO

I. **PURPOSE:**

A. Research

To specify procedures governing all research activities involving staff and inmates under the jurisdiction of the Rhode Island Department of Corrections (RIDOC).

B. Non-Medical Research

To specify procedures for the compilation, analysis, and distribution of statistical information, data, and trends affecting RIDOC.

C. Behavioral and Medical Research

To ensure that medical and/or behavioral research using RIDOC inmates or employees as subjects is consistent with established medical, legal, regulatory, and ethical standards for human research. Experimental medical treatment will only be administered if done strictly in accordance with Federal regulations.

This policy does not preclude treatment of an inmate based on the need for a specific medical procedure that is not generally available. A medical research proposal must include a designed path to treatment in the event a previously undiagnosed medical condition is discovered during the course of the project.

II. POLICY:

A. The Planning and Research Unit and Health Care Services support and engage in research which enhances the mission of RIDOC and which:

1. is relevant to RIDOC's program services and operations;

2. is utilized for the development of RIDOC program initiatives; and

3. does not subject staff and/or inmates to experimentation that is unethical.

B. Research is conducted according to the procedures listed below and in compliance with professional and scientific ethics and State and Federal guidelines for the use and dissemination of research findings. (See Code of Federal Regulations 45 CFR, Subpart C, Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as subjects, which as of this policy's effective date can be found at www.dhs.gov/ohrp/humansubjects/guidance.45cfr46.htm.)

C. RIDOC formally and officially encourages and cooperates with the research activities of professionals outside its jurisdiction.

D. Research shall be conducted in an orderly and effective manner and not interfere with the day-to-day operations of RIDOC facilities and/or units.

E. The request to engage in research may be denied if:

1. The research is not relevant to RIDOC program services and operation;

2. RIDOC does not have the staff resources and/or staffing allocation to support the research;

3. RIDOC does not have the financial resources available to support the research.

III. PROCEDURES:

A. Definitions

1. Behavioral research is any research, whether treatment is a component or not, that involves gathering information directly from inmates or staff (i.e., any surveys that are directly administered to inmates or staff regardless of content).

2. Medical research is any research that involves therapeutic or diagnostic intervention with inmates/patients (medical, behavioral health or dental) as it pertains to health care services.

3. Non-medical research is any research that does not involve gathering information directly from inmates or staff, nor research that involves therapeutic or diagnostic intervention with inmates. Non-medical research may include:

   Academic paper/project is conducted by university faculty and/or students who examine a topic that is relevant to RIDOC programs and services;

4. Vulnerable population is defined in 45 CFR 46 Subpart C (Prisoners): as any individual involuntarily confined or detained in a penal institution.

B. Planning and Research Unit:

1. The Planning and Research Unit is responsible for the coordination of all Departmental research and evaluation.

2. RIDOC's program and operational personnel assist the Planning and Research Unit in carrying out its research and evaluation tasks.

C. Requests for Research:

All requests for research and evaluation, including examination and analysis of secondary data, are submitted, in writing, to the Associate Director of Planning and Research. The Associate Director of Planning and Research reviews the request and makes a recommendation to the Director via the Assistant Director of Administration, for non-medical research and to the Medical Program Director for medical/behavioral research.

Failure to submit a comprehensive research proposal which complies with RIDOC's research standards may require the researcher to work with a research partner at RIDOC in order to have his/her proposal reconsidered.

1. Non-Medical

a. Student requests to conduct non-medical research should contain the names and contact information for the student's academic advisors/professors (specifically the name of school, address, phone number, and e-mail address).

b. Non-medical research requests are reviewed and approved or denied within sixty (60) days. The Associate Director of Planning and Research makes formal notification of a request's approval or denial in writing to the requesting researcher(s) and sends a copy of the notification letter to the requestor's academic advisor(s)/professor(s).

2. Medical/Behavioral

a. All requests for behavioral and medical research and evaluation are submitted, in writing, to the Associate Director of Planning and Research. S/he informs the individual requestor if there are any components of the proposed research project that require Medical

Research Advisory Group (MRAG) review. The Associate Director of Planning and Research participates in the MRAG review of behavioral research projects.

(1) For behavioral and medical research, the requestor shall:

(a) complete a RIDOC Health Care Services Medical Research Advisory Group Application/Update Report;

(b) submit proof of Institutional Review Board (IRB) approval for review unless otherwise approved by the Medical Program Director;

(c) if submitting an IRB approval, include a statement certifying that the IRB met the Federal Regulations (45 CFR 46.304) governing the composition of IRBs where prisoners are involved, specifically, "that at least one member of the Board shall be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity…"

(d) submit a complete research protocol;

(e) submit all consent forms, if applicable;

(f) provide funding source information and availability of funds to pay for programming needs (e.g., record pulls, time spent compiling reports with appropriate data fields, clinical provider time to participate and complete forms) with an estimated number of hours needed for the research project;

(g) a clear timeline for the project including anticipated start and end dates and any critical interim (milestone) dates;

(h) preferred RIDOC facilities or other locations to be accessed for research; and

(i) provide Indirect Cost Rate Agreement and indirect cost rate of five percent (5%) of funds requested; these funds may be requested to offset RIDOC operational and/or program allocations.

Exceptions to (a) through (i) must be approved by the MRAG and/or the Medical Program Director.

(2) For *federally-funded or United States Department of Health and Human Services (DHHS)-supported behavioral research,* the requestor must follow the procedures outlined above for medical research.

(3) For *behavioral research which is not federally-funded or DHHS-supported,* the requestor may choose to follow the procedures outlined above for medical research (i.e., obtaining external IRB approval for the project) or may choose to comply with the following standards *in addition to* those outlined in the Research Design Criteria (item III.D.) of this policy. The standards include:

(a) drafting a research proposal that adequately describes the issue(s) under investigation, including hypotheses to be tested, and providing theoretical support for the inclusion of specific assessments/questions that have been selected for use;

(b) demonstrating the researcher's qualifications to conduct the proposed research (e.g., previous research projects, academic background) and attaching a copy of the researcher's curriculum vitae;

(c) demonstrating appropriate measures to be taken to comply with the Health Care Confidentiality provisions of the Health Insurance Portability and Accountability Act (HIPAA); and

(d) demonstrating appropriate sampling procedures to ensure that findings will be generalizable (have a confidence level of approximately 95% and a confidence interval of no larger than ± 5%) and have a

low margin of error. Sample size should be appropriate for statistical analysis.

Exceptions to (a) through (d) may be approved by the MRAG and/or the Medical Program Director.

b. In all applicable cases, the requestor of behavioral or medical research projects should seek IRB approval prior to submitting a proposal to the Associate Director of Planning and Research. Medical research not approved by an IRB must state a reason for the absence of that approval.

(1) If the MRAG approves the research, the Medical Program Director or designee submits the MRAG's recommendation to the Director for final approval.

(2) Medical research requests will be reviewed within sixty (60) days of receipt. The Associate Director of Planning and Research notifies the requesting researcher of the Director's decision (project formally approved or project denied) in writing within seventy (70) days of receipt of his/her request.

(3) The Medical Program Director or designee provides an estimated number of personnel hours and the cost associated with the project to the Principal Investigator for allocation of funds to cover the Department's costs.

(4) The Medical Program Director has the authority to delay the start of a research project based upon the number of projects underway at any time.

D. Research Design Criteria:

Included in the original request is a detailed research proposal that is developed by a facility/unit/program manager or outside investigator in conjunction with the Associate Director of Planning and Research (non-medical), the Medical Program Director (medical/behavioral), or designees. This proposal should include the following elements:

1. A one-page abstract or summary of the research to be conducted which includes an overview of the project goals and objectives and measurable outcomes and satisfies the DHHS Guidelines for research involving prisoners (See Code of Federal Regulations 45 CFR, Subpart C, Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as subjects, which as of this policy's effective date can be found at www.-hhs.gov/ohrp/humansubjects/guidance.45cfr46.htm.)

2. RIDOC resources and personnel that may be needed for the study, including the name of the staff member who will serve as the Departmental liaison and monitor for the project. If Department personnel are needed for the study, the researcher shall provide detail pertaining to RIDOC staff's role in the proposed research and estimate the number of staff hours involved.

3. The sampling procedures for selecting inmate subjects or inmate records for the research, as well as criteria that will be used for sample selection.

4. The procedures for data collection and copies of research instruments to be used, including interview schedules, questionnaires, data collection forms, assessment tools, and/or tests.

5. A copy of the informed consent form to be used for behavioral or medical research. Informed consent forms must include the following sections:

   a. a statement describing the research;

   b. a description of how this research is relevant to RIDOC's program services and operations;

   c. a statement that if medical conditions previously undiagnosed are discovered during the course of the research, the project includes a designed path to treatment by RIDOC Health Care Services.

   d. a description of the potential risks and/or discomforts to subjects;

   e. for research involving more than minimal risk, an explanation as to whether compensation and medical treatment are provided if needed;

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

g. a statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefit to the inmate;

h. a description of how confidentiality of records/information will be maintained;

i. a description of the destruction of identification links and/or study documents and who has access to these documents;

j. a statement that confidentiality must be broken if information revealed is considered a threat to facility and/or community corrections security;

k. the name of and contact information for the person who answers questions about inmate subject's rights;

l. if inmate subjects will receive financial compensation for their participation, the amount of the compensation, and the frequency of payment (e.g., one payment of $_____; payment of $_____ per activity; etc.) which will be paid to the inmate in accordance with RIDOC policy 2.09-1 DOC, Accountability of Inmate Money/Checks, or a successive policy.

NOTE: the use of gift cards is prohibited;

In addition, the consent document should be written at an elementary-school reading level. The person obtaining consent must provide the inmate the opportunity to ask any questions related to the study before the inmate signs the consent form.

6. The security procedures to be followed to protect the privacy of participants, which will comport with Department policy and Federal Regulations (45 CFR 46) on inmate privacy rights.

7. Any prospective impact on Departmental operations, including staffing required.

8. A description of the finished product.

E. Research Process:

1. Research within the Department must comply with acknowledged professional and scientific ethics, as well as State and Federal guidelines, which govern the use and dissemination of research findings.

2. Completed proposals are submitted to the Associate Director of Planning and Research for an initial review. The Associate Director of Planning and Research sends a copy of the proposal to the appropriate Assistant Director (Institutions & Operations, or Administration or Rehabilitative Services), the Medical Program Director, affected facility Warden(s), Associate Director of Community Corrections, or appropriate Unit Managers. The Warden(s), Associate Director of Community Corrections, or appropriate Unit Manager shall forward documentation to the Associate Director of Planning and Research indicating they have reviewed the research request and if such research shall have an impact on their facility and/or community corrections.

3. After an initial review of non-medical research proposals, the Associate Director of Planning and Research submits the proposal to the Assistant Director of Administration (see sample form at Attachment 1). If the Assistant Director supports the project, s/he submits the proposal to the Director for final approval.

4. For medical/behavioral research, the Associate Director of Planning and Research submits the proposal to the Medical Program Director, and sends a copy to the affected facility Warden(s), for MRAG review (see sample form at Attachment 2). After MRAG review and approval, the Medical Program Director submits the behavioral or medical research proposal to the Director for final approval.

5. For medical/behavioral research, the Associate Director of Planning and Research forwards the proposal to the MRAG for review and approval regarding compliance with IRB approval and Code of Regulations 45 CFR, Subpart C, Medical and Behavioral Research, Prisoners as research subjects.

6. If the Director gives final approval to the project, the Associate Director of Planning and Research notifies the researcher in writing. In the case of student researchers, a copy of the notification letter is also sent to the student's academic advisor/professor.

7. Before the research project begins, all persons who will be conducting evaluative research are informed of, and agree in writing to conform to, all applicable RIDOC policies including, but not limited to, those pertaining to the confidentiality of information obtained (see Confidentiality Pledge at Attachment 3). In addition, students must complete online training regarding working with human subjects (e.g., cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp) and provide a copy of the training completion certificate to the Associate Director of Planning and Research before they begin work on a research project. All persons conducting research in a facility must also pass security clearances [e.g., Bureau of Criminal Identification (BCI) checks, National Crime Information Center (NCIC) checks]. All proposed changes in study personnel must be made in writing to the Associate Director of Planning and Research who, in turn, informs the Medical Program Director or designee.

   In addition, they will be required to attend "Boundary" training from the Training Academy.

8. RIDOC's Director or designee may suspend research or terminate a study prior to its completion due to an emergency or disruption in the facility(ies).

9. All research data collected that identifies individual staff and/or inmates is subject to the same confidentiality and security standards required for case records and personnel files (i.e., stored in locked files and inaccessible to persons other than those conducting/assisting in the research).

10. The Associate Director of Planning and Research and the Medical Review Advisory Group, if necessary, is provided an opportunity to comment on the final draft of research results prior to its publication. Comments are made, in writing, and sent to the researcher and academic advisor, where applicable. The final draft is reviewed by the Associate Director of Planning and Research (non-medical) and/or the Medical Program Director (medical and behavioral). However, RIDOC does not interfere with the integrity of the data as part of this process. In all cases, RIDOC will be noted as the location where the research took place as will, if applicable, RIDOC staff participation in the research project.

11. Final products resulting from all research (non-medical, medical and behavioral) conducted according to this policy (i.e., manuscripts, abstracts,

posters, videos, etc.) must be submitted to the Associate Director of Planning and Research prior to submission for publication/presentation/dissemination.

12. RIDOC may duplicate or disseminate final research reports to RIDOC staff as appropriate (e.g., research abstracts posted on RIDOC's website).

F. Compensation to Inmate Subjects

1. If the researcher has received approval to compensate inmate subjects for their participation, the Associate Director of Planning and Research or designee notifies Inmate Accounts staff.

2. The researcher provides the name(s) of the inmate(s), his/her/their inmate identification (ID) number(s) and the amount(s) payable to the inmate(s).

3. In the case of several inmates participating in research and being compensated, the researcher submits an aggregate check made payable to "RIDOC Inmate Accounts" to the Inmate Accounts staff.

G. Violations of Research Regulations

1. Permission to conduct the current study and any future research may be withdrawn for violation of this policy or of any other RIDOC policies during the course of a research project.

2. Violations of regulations that address confidentiality of inmate records information may subject the violator to civil and/or criminal liability.

H. Research Log:

1. The Planning and Research Unit maintains a log summary and index of all research work products developed.

2. Copies of all completed studies and reports (including behavioral and medical) are maintained by the Planning and Research Unit for distribution to appropriate agencies/individuals on request.

I. Program Development Research:

The Planning and Research Unit and Health Care Services are organized to coordinate and monitor new and/or experimental program initiatives (non-medical and medical, respectively) at all levels of command.

1. RIDOC recognizes the importance of research, both internally initiated and carried on by Departmental personnel, and externally initiated and carried on by outside agencies (e.g. the American Correctional Association, the Governor's Office, various Legislative committees, etc.). The Planning and Research Unit and Health Care Services staffs coordinate these projects and provide appropriate expertise in a timely manner.

2. The Planning and Research Unit and Health Care Services staffs maintain continuous contact with all facility/unit/program managers in both advisory and planning capacities. Operational personnel assist Planning and Research staff in carrying out research and evaluation. Assistance includes determining research needs, establishing priorities, and collecting data.

3. The Planning and Research Unit and Health Care Services staffs keep abreast of current and evolving professional trends and developments by attending local, regional, and national meetings and conferences, as well as maintaining familiarity with existing professional literature.

J. Statistical Data Analysis:

The Planning and Research Unit prepares briefing materials, statistical reports, analyses, and evaluations for RIDOC's Director to assist with budgetary, operational, and policy decisions, as well as new program initiatives.

1. The Planning and Research Unit assists other branches of state government, particularly legislative bodies and committees, by providing trends, statistics, and operational parameters.

2. The Planning and Research Unit coordinates with the Financial Resources Unit for the preparation of policy and fiscal impact statements as set forth in policy 2.20-4 DOC, Fiscal Notes/Prison Impact Statements, or a successive policy.

RHODE ISLAND DEPARTMENT OF CORRECTIONS
Planning & Research Unit
18 Wilma Schesler Lane, Dix Bldg.2nd floor
Cranston, RI 02920
Phone: (401) 462-3920 Fax: (401) 462-1507

Form 2A: Non-medical Research Project Review Form

Title of Research Study:

Purpose: (Is Abstract Attached? ☐Yes ☐No)

Study Duration: _____

Reviewed by Planning & Research: Date: _____ Approved ☐ Denied ☐

Associate Director, Planning & Research: _____

Comments:

To: Associate Director of Planning and Research Date: _____

cc: Affected facility Warden(s) or Administrator Date: _____

Reviewed by Asst Dir. of Administration Date: _____ Approved [ ] Denied [ ]

Assistant Director, Administration Signature: _____

To: Director Date: _____

Reviewed by Director: Date: _____ Approved [ ] Denied [ ]

Director's Signature: _____

After completing form, please return to Planning & Research Unit.

RHODE ISLAND DEPARTMENT OF CORRECTIONS
Planning & Research Unit
18 Wilma Schesler Lane, Dix Bldg.2nd floor
Cranston, RI 02920
Phone: (401) 462-3920 Fax: (401) 462-1507

Form 2B: Behavioral/Medical Research Project Review Form

Title of Research Study:

Purpose: (Is Abstract Attached? ☐Yes ☐No)

Study Duration: _____

Initial Review by Planning & Research: Date: _____ Meets Criteria in Policy ☐

Associate Director, Planning & Research: _____

To: Interdepartmental Program Manager Date: _____
cc: Medical Program Director Date: _____
Warden (affected facility[ies]) Date: _____

Reviewed by MRAG: Date: _____ Approved [ ] Denied [ ]

Signature: _____

NOTE TO WARDEN(S): Please forward (in writing) any comments/concerns you have regarding the above-described research project to the Medical Program Director with a copy to the Associate Director of Planning and Research.

Comments:

To: Director Date: _____

Reviewed by Director: Date: _____ Approved [ ] Denied [ ]

Director's Signature: _____

After completing form, please return to Planning & Research Unit.

RHODE ISLAND DEPARTMENT OF CORRECTIONS

CONFIDENTIALITY PLEDGE

Individuals conducting research at the Department have an ethical and a legal obligation to keep confidential all information received from and/or about persons with whom the Department is currently and/or was previously involved or otherwise has knowledge. Said individuals are therefore required to sign this Confidentiality Pledge. Unauthorized disclosure of confidential information by such individuals could result in a fine and/or imprisonment and/or civil liabilities as prescribed by law as well as termination of the volunteer work/internship.

I hereby pledge that I shall abide by this assurance of confidentiality and acknowledge and agree to the following stipulations:

1. I understand and support the Department's firm commitment to the principle of confidentiality of case information.

2. I understand for the purposes of all Departmental policies on confidentiality that researchers shall be defined as all current and former researchers.

3. I agree to keep confidential all information contained in Departmental records and shall only disclose such information as allowed by law or by Departmental policy.

4. I shall safeguard from unauthorized disclosure all information retrieved from RIDOC and/or RIDOC computers as well as any assigned password(s) used to gain access to any database.

5. I agree to consult with my Departmental supervisor prior to disclosure if there is any question concerning the authority to release specific confidential information.

6. I understand that violation of the privacy rights of individuals through unauthorized discussion, disclosure, dissemination, or access to personal information could subject me to early termination of any research project as well as civil and/or criminal penalties.

7. I understand that possessing personal notes, records, duplicate files, or any information received from and/or about persons currently or previously involved with the Department is prohibited and that case information is to be recorded in appropriate Departmental records per Department policy.

8. I understand that all information received from and/or about persons currently or previously involved with the Department is the property of the Department and that any such information will be relinquished to the Department upon the completion of my research.

_____
PRINTED NAME

_____ _____
SIGNATURE DATE

_____ _____
WITNESS DATE