RHODE ISLAND DEPARTMENT OF CORRECTIONS
POLICY AND PROCEDURE

	POLICY NUMBER: 6.06-3 DOC	EFFECTIVE DATE: 01/28/08	PAGE 1 OF 11
	SUPERCEDES: 6.06-2 DOC	DIRECTOR: 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 DOC, Accountability of Inmate Money/Checks; 2.20 DOC, Fiscal Notes/Prison Impact Statements; 6.05-2 DOC, Program Evaluation; 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

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

I. **PURPOSE:**

A. Non-Medical Research

To specify procedures for the compilation, analysis, and distribution of statistical information, data, and trends affecting the Rhode Island Department of Corrections (RIDOC).

B. Behavioral and Medical Research

To ensure that medical and/or behavioral research using offenders or employees as subjects is consistent with established medical, legal, regulatory, and ethical standards for human research.

This policy does not preclude treatment of an offender based on the need for a specific medical procedure that is not generally available.

C. Definitions

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

2. Medical research is any research that involves therapeutic or diagnostic intervention with offenders.

3. Research partner is an experienced researcher (e.g., professor, graduate student) who can provide instruction and guidance to novice researchers around the topics of research methodology, confidentiality, sampling, data collection, data analysis/measurement, etc.

4. Program development research is that which seeks to support building and/or enhancing new initiatives within RIDOC.

II. POLICY:

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

1. is relevant to program services and operations;

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

3. does not subject staff and/or offenders 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.

III. PROCEDURES:

A. Planning and Research Unit:

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

2. Operational personnel of the RIDOC assist the Planning and Research Unit in carrying out its research and evaluation tasks.

B. Requests for Research:

All requests for research and evaluation, to include examination and analysis of secondary data, are submitted, in writing, to the Associate Director of Planning and Research. S/he 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.

1. Non-Medical

a. Requests for non-medical research by students should contain names and contact information of students' academic advisors/professors (specifically the name of school, address, phone number, and e-mail address).

b. Non-medical research requests will be reviewed and approved or denied within one (1) month. Formal notification of approval or denial will be made in writing to the requesting researcher(s), with a copy to the academic advisor(s)/professor(s), by the Associate Director of Planning and Research.

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. After an initial review, s/he will forward the request to the Medical Research Advisory Group (MRAG). The Associate

Director of Planning and Research will participate in the MRAG review of behavioral research projects.

(1) For *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 IRG approval, include a statement certifying that the IRB met the Federal Regulations (45 CFR 46.304) governing the composition of the IRB's 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; and

(e) submit all consent forms, if applicable.

Exceptions to (a) through (e) 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.C.) 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 will be taken to comply with 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.

(4) Failure to submit a comprehensive research proposal which complies with these standards as well as those described in item III.C. of this policy will require the researcher to work with a research partner in order to have the proposal reconsidered.

b. In all applicable cases, the requestor of behavioral or medical research should seek IRB approval prior to submitting the proposal to the Associate Director of Planning and Research. Medical research not approved by an IRB will be prohibited at RIDOC or must state reason for lack of IRB 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. Formal notification of approval/denial by the Director will be made in writing to the requesting researcher by the Associate Director of Planning and Research within seventy (70) days of receipt of request.

C. Research Design Criteria:

Included in the original request for research 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.dhs.gov/ohrp/humansubjects/guidance.45cfr46.htm.)

2. Department resources and personnel that may be needed for the study, including the name of the staff member who will serve as the institutional liaison and monitor for the project.

3. The sampling procedures for selecting offender subjects or offender 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 potential risks and/or discomforts to subjects;

c. a description of any benefits of the research;

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

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

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

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

h. an explanation of who to contact for answers to questions about inmate subject's rights;

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

j. a statement that confidentiality must be broken if information revealed is considered a threat to institutional security.

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 prior to signing the 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 offender privacy rights.

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

8. A description of the finished product.

D. Research Process:

1. Research within the Department is in compliance 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.

3. After initial review, the Associate Director of Planning and Research submits the proposal (for non-medical research) to the Director via the Assistant Director of Administration (see sample form at Attachment 1). The Associate Director of Planning and Research also forwards a copy of the proposal to the affected facility Warden(s). 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 [with a copy to the affected facility Warden(s)] for MRAG review (see sample form at Attachment 2). After review and MRAG approval, the Medical Program Director submits the proposal for behavioral or medical research to the Director for final approval.

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

6. Prior to commencing research, all persons conducting evaluative research are informed of and agree in writing to conform to all applicable policies with emphasis on the confidentiality of information obtained (see Confidentiality Pledge at Attachment 3). In addition, students must complete an online training (e.g., cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp) regarding working with human subjects prior to beginning research and provide a copy of the completion certificate to the Associate Director of Planning and Research. 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].

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

8. All research data collected that identifies individual staff and/or offenders 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).

9. RIDOC will be provided with an opportunity to comment on the final draft prior to its publication. Comments will be made, in writing, and sent to the researcher and academic advisor, where applicable. The final draft will be reviewed by the Associate Director of Planning and Research (non-medical) and/or the Medical Program Director (medical and behavioral). However, RIDOC will not interfere with the integrity of the data as part of this process. Copies of final products (non-medical, medical and behavioral) to include but not be limited to reports, presentations, manuscripts are to be forwarded to the Associate Director of Planning and Research.

10. Final products resulting from research conducted according to this policy (i.e., manuscripts, abstracts, posters, videos, etc.) must be submitted to the Associate Director of Planning and Research (non-medical) prior to submission for publication/presentation/dissemination.

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

E. 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 will provide 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 to Inmate Accounts staff an aggregate check made payable to "RIDOC Inmate Accounts".

F. 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 other RIDOC policies in the course of the research.

2. Violations of regulations with respect to inmate record information may subject the violator to civil and/or criminal liability.

G. 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.

H. 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, and so forth). The Planning and Research Unit and Health Care Services staff coordinate these projects and provide appropriate expertise.

2. The Planning and Research Unit and Health Care Services staff maintain continuous contact with all facility/unit/program managers in both advisory and planning capacities. Operational personnel assist Planning and Research personnel 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 staff 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.

I. Statistical Data Analysis:

The Planning and Research Unit prepares briefing materials, statistical reports, analyses, and evaluations for the Director of Corrections 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 DOC, Fiscal Notes/Prison Impact Statements, or a successive policy.

RHODE ISLAND DEPARTMENT OF CORRECTIONS
Planning & Research Unit
1 Wilma Schesler Lane, Pinel 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 Project:

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

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

Associate Director, Planning & Research: _____

Comments:

To: Ellen Evans Alexander Date:
cc: Affected facility Warden(s)

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

Assistant Director, Administration Signature: _____

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

To: Ashbel T. Wall Date:

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

Director's Signature: _____

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

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Form 2B: Behavioral/Medical Research Project Review Form

Title of Research Project:

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

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

Associate Director, Planning & Research: _____
Erin L. Boyar

To: Michael Poshkus, MD Date:
Chair, Medical Research Advisory Group
cc: Affected facility Warden(s)

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: Ashbel T. Wall Date:
Reviewed by Director: Date:_____ Approved [ ] Denied [ ]

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