



RHODE ISLAND DEPARTMENT OF CORRECTIONS

POLICY AND PROCEDURE

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|  | POLICY NUMBER: 6.06-5 DOC | EFFECTIVE DATE: 11/02/2020 | PAGE 1 OF 11 |
| | SUPERSEDES: 6.06-4 DOC | DIRECTOR: <div style="text-align: right; font-size: small;">Please use BLUE ink.</div>  | |
| SECTION: INFORMATION SYSTEMS AND RESEARCH | | SUBJECT: RESEARCH | |
| AUTHORITY: Rhode Island General Laws (RIGL) § 42-56-10 (22), Powers of the director | | | |
| REFERENCES: The most recent versions of RIDOC policies 2.09 DOC, Accountability of Inmate Money/Checks ; 2.20 DOC, Fiscal Notes/Prison Impact Statements ; 6.05 DOC, Program Evaluation ; 9.18 DOC, Introduction of Unauthorized Items into the Adult Correctional Institutions ; 9.23 DOC, Access to ACI Facilities by Staff and Persons Providing Services to RIDOC ; 9.24 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 ensure that non-medical research requests (compilation and analysis of statistical information, data and trends) involving staff and/or inmates is consistent with established legal, regulatory and ethical standards of human research.

C. Behavioral and/or 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.

II. POLICY:

- A. The Planning and Research Unit is responsible for the coordination of all Departmental research and evaluation.
- B. 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.
- C. RIDOC supports and engages in research which enhances its mission and which:
 - 1. Is relevant to RIDOC's program services and operations;
 - 2. Is utilized for the development of RIDOC program initiatives;
 - 3. Does not subject staff and/or inmates to experimentation that is unethical; and
 - 4. Contributes to the general knowledge in the corrections field.
- D. RIDOC formally and officially encourages and cooperates with the research activities of professionals outside its jurisdiction.
- E. The request to engage in research may be denied if:
 - 1. The research is not relevant to RIDOC program services and operations;
 - 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; and/or
 - 4. The research does not contribute to the general knowledge in the corrections field.

- F. Research is conducted according to the procedures listed in this policy and in compliance with professional and scientific ethics and State and Federal guidelines for the use and dissemination of research findings (see [45 CFR part 46, Subpart C](#)).
- G. Experimental medical treatment will only be administered if done strictly in accordance with Federal regulations.
- H. This policy does not preclude treatment of an inmate based on the need for a specific medical procedure that is not generally available.
- I. A medical research proposal must include a designed path to treatment in the event a previously undiagnosed medical condition is discovered during the project.

III. DEFINITIONS:

- 1. Research – the systematic empirical investigation of phenomena, both quantitative and qualitative.
- 2. Behavioral research - any research, whether treatment is a component or not, that involves gathering information from inmates or staff (i.e., any surveys that are directly administered to inmates or staff regardless of content).
- 3. Medical research - any research that involves therapeutic or diagnostic intervention with inmates/patients (medical, behavioral health or dental) as it pertains to health care services.
- 4. Non-medical research - any research that does not involve gathering information directly from inmates or staff, nor research that involves therapeutic or diagnostic intervention with inmates.
- 5. Institutional Review Board (IRB) - an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.
- 6. Medical Research Advisory Group (MRAG) – an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of RIDOC.

7. Vulnerable population - any individual involuntarily confined or detained in a penal institution as defined in [45 CFR part 46, Subpart C](#).

IV. PROCEDURES:

A. Requests for Research

1. 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 request shall be consistent with Section [IV.D](#), Research Design Criteria, of this policy.
2. 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 MRAG for medical/behavioral research.
3. Failure to submit a comprehensive research proposal will require the researcher to submit additional information or revise his/her proposal to comply with RIDOC's research standards in order to have his/her proposal reconsidered.
4. The Planning and Research Unit maintains a log summary and index of all research work products developed.
5. Copies of all findings (including behavioral and medical) are maintained by the Planning and Research Unit for distribution to appropriate agencies/individuals on request.

B. Student Requests

Student requests to conduct 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).

Student 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).

C. Medical/Behavioral Research

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 MRAG review.

1. For behavioral and medical research, the requestor shall:
 - a. Complete a RIDOC Health Care Services [MRAG Application/Update Report](#);
 - b. Seek Institutional Review Board (IRB) approval prior to submitting a proposal and submit IRB proof of approval 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. ; The requestor shall also 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...”
 - c. Submit a complete research protocol;
 - d. Submit all consent forms, if applicable (see Section [IV.C.2](#));
 - e. 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;
 - f. A clear timeline for the project including anticipated start and end dates and any critical interim (milestone) dates;
 - g. Preferred RIDOC facilities or other locations to be accessed for research; and
 - h. Provide an indirect cost rate of five percent (5%) of the direct cost funding amount and the negotiated indirect cost rate currently in

effect. The indirect cost rate of five percent (5%) is requested to offset RIDOC operational and/or program allocations. The indirect cost rate will be assessed against direct costs that include salary, fringe benefits, supplies, consultants, and training associated with the research project.

The Medical Program Director/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.

- i. For federally-funded behavioral or medical research, the requestor must follow the procedures outlined above for medical research.
- j. For behavioral or medical research which is not federally-funded, 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:
 - (1) 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;
 - (2) 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;
 - (3) Demonstrating appropriate measures to be taken to comply with the Health Care Confidentiality provisions of the Health Insurance Portability and Accountability Act (HIPAA); and
 - (4) 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 $\pm 5\%$) and have a low margin of error. Sample size should be appropriate for statistical analysis.

2. Consent Documentation - A copy of the informed consent form to be used for behavioral or medical research is required. 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. 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 and/or general corrections knowledge;
 - 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;

1. 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 the most recent version of RIDOC policy 2.09 DOC, [Accountability of Inmate Money/Checks](#).

NOTE: The use of gift cards is prohibited.

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 their designees. This proposal shall include the following elements:

1. Summary - A one-page abstract or summary of the research to be conducted which includes an overview of the scope of work, project goals, objectives and measurable outcomes and satisfies the United States Department of Health and Human Services (DHHS) Guidelines for research involving prisoners (see [45 CFR part 46, Subpart C](#)).
2. Resources - 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. Sampling - 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. Data Collection - 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. Security - The security procedures to be followed to protect the privacy of participants' data, which will comport with Department policy and Federal Regulations on inmate privacy rights.

6. Operations and Financial Impact - Any prospective impact on RIDOC operations and costs, including staffing required.
 7. Description - 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.
 - a. The Associate Director of Planning and Research reviews research proposals (medical/behavioral and non-medical) for compliance with RIDOC's Research Policy. S/he communicates with the entity that submitted the research request if there are areas where they are not in compliance with this research policy and 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.
 - b. 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 and [Form 2A – Non-medical Research Project Review Form](#) to the Assistant Director of Administration. If the Assistant Director supports the project, s/he submits the proposal to the Director for final approval.
 4. After an initial review of medical/behavioral research proposals, the Associate Director of Planning and Research submits the proposal and [Form 2B – Behavioral/Medical Research Project Review Form](#) to the MRAG members prior to the MRAG meeting for review. A summary of

the proposal is also sent to the affected facility Warden(s) and/or the Associate Director Community Corrections.

- a. After MRAG review and approval the Medical Program Director/designee shall sign the Behavioral/Medical Research Review form. The research request shall then be forwarded to the Director for his/her review and final approval.
 - b. 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.
 - c. 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.
5. 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](#)).
 6. Students must complete online training regarding working with human subjects 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.
 7. All persons conducting research in a facility must complete an [Access to Facilities Application](#). As part of the [Access to Facilities Application](#), everyone must pass security clearances [i.e., Bureau of Criminal Identification (BCI) checks, National Crime Information Center (NCIC) checks]]. Prior to entering a secure facility, research personnel shall also attend New Employee Orientation (NEO) at the RIDOC Training Academy.
 8. RIDOC's Director/designee may suspend research or terminate a study prior to its completion at any time for any reason that may include an emergency or disruption in the facility(ies) or violations of this or any other RIDOC policy.

9. If the researcher has received approval to compensate inmate subjects for their participation, the Associate Director of Planning and Research/designee notifies Inmate Accounts staff.
10. 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).
11. 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.
12. 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).
13. For all research projects lasting one year or more, updates shall be provided to the Associate Director of Planning and Research biannually. The principal researcher shall ensure that they are up-to-date with IRB approval. Updates shall include any changes in principal researcher or research staff, scope of work, or research termination date as well as any issues that have arisen.
14. The Associate Director of Planning and Research and the MRAG, if necessary, must be provided the 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).
15. 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, and/or dissemination.
16. RIDOC may duplicate or disseminate final research reports to RIDOC staff as appropriate (e.g., research abstracts posted on RIDOC's website).