OF RHODE ISLAND	RHODE ISLAND POLICY AND P	DIRECTOR:	
POLICY	EFFECTIVE	SUBJECT:	Saler J.
NUMBER: 6.06-7 DOC	DATE: 01/10/2024	RESEARCH	
LAST REVIEWED: 11/2023SECTION: INFORMATION SYSTEMS AND RESEARCHSUPERSEDES: 6.06-6			
AUTHORITY: Rhode Island General Laws (RIGL) § 42-56-10 (22), Powers of the director			
<u>REFERENCES</u> : The most recent versions of RIDOC policies 2.09 DOC, <u>Accountability of</u>			
Inmate Money/Checks ; 2.20 DOC, <u>Fiscal Notes/Prison Impact Statements</u> ; 6.05 DOC, Program Evaluation; 9.18 DOC, Introduction of Unauthorized Items into the Adult			
Correctional Institutions; 9.23 DOC, Access to ACI Facilities; 9.24 DOC, Entry to/Exit from			
Secure Facilities; 9.49-5 DOC, PREA (Prison Rape Elimination Act) Policy; Federal			
Regulations on Medical Research in Correctional Institutions, 45 CFR 46, Rev. 10/01/94 45			
CFR Parts 160 and 164; NCCHC Standards J-G-06, Medical & Other Research; P-72, Medical			
Research; DoIT Encryption Data User Agreement			
INMATE/PUBLIC ACCESS: YES AVAILABLE IN SPANISH: YES			

I. **PURPOSE:**

- A. To specify procedures governing **all** research activities involving staff and offenders under the jurisdiction of the Rhode Island Department of Corrections (RIDOC) including the Adult Correctional Institutions, Adult Probation and Parole, and Home Confinement.
- B. To ensure that research requests involving staff and/or offenders are consistent with established medical, legal, regulatory and ethical standards of human research.

II. <u>POLICY</u>:

- A. The Planning and Research Unit is responsible for the coordination of all Departmental research and evaluation to include, but not limited to, surveys, opinions, evaluations, and requests for data collection involving staff, inmates, and/or offenders under community supervision.
- 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:
 - 1. is relevant to RIDOC's program services and operations;
 - 2. is utilized for the development of RIDOC program initiatives;
 - 3. does not subject offenders to experimentation that is unethical; and
 - 4. contributes to the general knowledge in the corrections field including community corrections.
- D. RIDOC formally and officially encourages and cooperates with the research activities of professionals outside its jurisdiction including support for an offender's continuation of participation in community-based research, and consultation with the community-based researchers so that the withdrawal is done without harming the health of the offender.
- E. 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 (see <u>45 CFR part 46</u>, <u>Subpart C</u>).
- F. Internal requests from RIDOC staff involving outside agencies must be approved in accordance with the provisions of this policy.
- G. 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).
- H. RIDOC's Director/designee may suspend research or terminate a study prior to its completion at any time for any reason that may include, but is not limited to,

an emergency or disruption in any facility or violations of this or any other RIDOC policy.

- I. The Director makes the final decision on all research requests.
- J. Violation of any RIDOC policy, data use/sharing agreement, or memorandum of understanding/agreement, whether formal or informal, will result in the termination of the project or study. This includes, but is not limited to, misuse of RIDOC data for purposes outside the scope of work, transferring the data to an entity not party to the agreement, or linking personally identifiable information (PII) or protected health information (PHI) to additional data sets outside of the original agreement/scope of work. Violations may impact future ability to engage in research with RIDOC and may involve legal action or other sanctions depending on the egregiousness of the breach of the agreement or policy.
- K. If data received or collected from RIDOC is published in a peer-reviewed journal without approval in accordance with the provisions of this policy, RIDOC retains the right to contact the journal to advise them of said breach.
- L. Complaints may be filed with the Institutional Review Board (IRB) of interest for research misconduct, if applicable.

III. **DEFINITIONS:**

- 1. **<u>Research</u>** the systematic empirical investigation of phenomena, both quantitative and qualitative.
- 2. <u>Behavioral research</u> any research, whether treatment is a component or not, that involves gathering information from offenders or staff (i.e., any surveys that are directly administered to offenders or staff regardless of content).
- 3. <u>Medical research</u> any research that involves therapeutic or diagnostic intervention with offenders (medical, behavioral health, or dental) as it pertains to health care services.
- 4. **<u>Non-medical research</u>** any research that does not involve therapeutic or diagnostic intervention with offenders or staff.
- 5. <u>Institutional Review Board (IRB)</u> 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. <u>Medical Research Advisory Group (MRAG)</u> 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. <u>**Vulnerable population**</u> any individual involuntarily confined or detained in a penal institution as defined in <u>45 CFR part 46, Subpart C.</u>

IV. **<u>PROCEDURES</u>**:

- A. <u>Requests for Research</u>
 - 1. All requests for research and evaluation, including examination and analysis of secondary data, interviews, surveys, opinions, and evaluations, are submitted via the web portal to the Administrator of Planning and Research or designee. The request shall be consistent with Section <u>IV.D.</u>, Research Design Criteria, of this policy.
 - 2. 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. Subsequent failure(s) to submit a comprehensive research request and/or respond to revision requests may result in denial of the request.
 - 3. The Administrator of Planning and Research or designee 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.
- B. <u>Student Requests</u>
 - 1. Student requests to conduct research shall contain the names and contact information for the students' academic advisors/professors (specifically the names of schools, addresses, phone numbers, and e-mail addresses) as well as any other documentation deemed necessary by the Administrator of Planning and Research or designee (e.g., IRB approval).

- 2. Complete student request packets are reviewed and approved or denied within sixty (60) business days, although execution of agreements may take longer.
- 3. The Administrator of Planning and Research or designee 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, as well as the <u>MRAG Research Update form</u> and <u>MRAG Completed Research form</u>, to the requestor's academic advisor(s)/professor(s).

C. <u>Medical/Behavioral Research</u>

- 1. All requests for behavioral and medical research and evaluation are submitted via the web portal to the Administrator of Planning and Research or designee. S/he informs the individual requestor if there are any components of the proposed research project that require MRAG review.
- 2. Experimental medical treatment will only be administered if done strictly in accordance with Federal regulations.
- 3. This policy does not preclude treatment of an offender based on the need for a specific medical procedure that is not generally available.
- 4. The Medical Program Director or designee has the authority to delay the start of a research project based upon the number of projects underway at any time.
- 5. For behavioral and medical research, the requestor shall:
 - a. Complete a RIDOC <u>MRAG Research Application form</u>.
 - b. Seek Institutional Review Board (IRB) approval prior to submitting a final proposal, although discussion with Planning and Research staff before submission is encouraged. A copy of the IRB application as well as proof of IRB approval shall be submitted to the Administrator of Planning and Research or designee. Primary data collection 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 (<u>45 CFR 46.304</u>) 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 <u>IV.C.6</u>);
- 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. For research that would create an undue hardship on the Department, the Medical Program Director or designee may ask that the researcher 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.

<u>NOTE</u>: 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 <u>IV.D.</u>) 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 (CV);
- (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 <u>+</u> 5%) and have a low margin of error. Sample size should be appropriate for statistical analysis.
- 6. <u>Consent Documentation</u> 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 offender the opportunity to ask any questions related to the study before the offender 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 offender;
- 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. The name and contact information of the person who answers questions about offender subject's rights;
- k. A statement that confidentiality must be broken if information revealed is considered a threat to self, others, facility and/or community corrections security. Threats also include, but are not limited to, all Prison Rape Elimination Act (PREA) allegations of sexual abuse or sexual harassment;

<u>NOTE</u>: For PREA allegations and threats, please refer to the most recent version of RIDOC policy 9.49 DOC, PREA (Prison Rape Elimination Act) Policy, for reporting requirements;

- 1. A statement that all allegations of sexual abuse and sexual harassment shall be reported immediately to the nearest Superior Officer, Shift Commander, Special Investigations Unit, or the Office of Inspection;
- m. If offender 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 offender in accordance with the most recent version of RIDOC policy 2.09 DOC, <u>Accountability of Inmate Money/Checks</u>. Financial compensation shall be paid in the form of money order or check only. No other forms of

compensation (e.g., gift cards, stamped envelopes, food) are allowed.

- n. Staff compensation for participation in research studies is strictly prohibited.
- 7. Completed medical research proposals will be provided an initial review within sixty (60) business days of receipt. The Administrator of Planning and Research or designee notifies the requesting researcher of the Director's decision [project formally approved, approved pending revisions or the execution of agreement(s) or project denied] in writing within seventy (70) days of receipt of his/her proposal.

D. <u>Research Design Criteria</u>

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 Administrator of Planning and Research (non-medical), the Medical Program Director (medical/behavioral), or their designees. This proposal shall include the following elements:

- 1. <u>Summary</u> 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 <u>45 CFR part 46, Subpart C</u>).
- 2. <u>Resources</u> 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. <u>Sampling</u> 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. <u>Data Collection</u> 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. <u>Security</u> The security procedures to be followed to protect the privacy of participants' data, which will comport with Department policy and Federal Regulations on offender privacy rights.
- 6. <u>Operations and Financial Impact</u> Any prospective impact on RIDOC operations and costs, including staffing required.
- 7. <u>Description</u> A description of the finished product.

<u>NOTE</u>: A medical research proposal must include a designed path to treatment in the event a previously undiagnosed medical condition is discovered during the project.

E. <u>Research Process</u>

- 1. Completed proposals are submitted via the web portal to the Administrator of Planning and Research or designee for initial review by affected Departmental administrators/designees.
- 2. 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 <u>Confidentiality Pledge</u>).
- 3. The request to engage in research may be denied if:
 - a. The research is not relevant to RIDOC program services and operations;
 - b. RIDOC does not have the staff resources and/or staffing allocation to support the research;
 - c. RIDOC does not have the financial resources available to support the research; and/or
 - d. The research does not contribute to the general knowledge in the corrections field.
- 4. Students conducting their own primary data collection under the supervision of a faculty member must complete online training regarding working with human subjects and provide a copy of the training

completion certificate to the Administrator of Planning and Research or designee before they begin work on a research project.

- 5. All persons conducting research in a facility must complete an <u>Access to</u> <u>Facilities Application</u>. As part of the <u>Access to Facilities Application</u>, everyone must pass security clearances [i.e., Bureau of Criminal Identification (BCI) checks, National Crime Information Center (NCIC) checks and Court records checks]. Prior to beginning data collection, research personnel shall also attend New Employee Orientation (NEO) at the RIDOC Training Academy. The Administrator of Planning and Research or designee shall submit these applications for all individuals conducting research in the facilities. An audit should be performed every six (6) moths to determine whether researchers continue to require access to facilities. If it is determined that an individual who accesses the facilities for research purposes has not completed NEO, access to facilities will be suspended.
- 6. If the researcher has received approval to compensate offender subjects for their participation, the Administrator of Planning and Research or designee notifies Inmate Accounts staff.

NOTE: Staff compensation for participation in a research study is strictly prohibited.

- 7. The researcher provides the name(s) of the offender(s), his/her/their inmate identification (ID) number(s) and the amount(s) payable to the offender(s).
- 8. In the case of several offenders participating in research and being compensated, the researcher submits an aggregate check or money order made payable to "RIDOC Inmate Accounts" to the Inmate Accounts staff.
- 9. For all research projects lasting one year or more, updates shall be provided to the Administrator of Planning and Research or designee in six (6) month intervals from the start of the research.
 - a. The principal researcher shall submit a completed <u>MRAG Research</u> <u>Update form</u>, to include requested documentation, and shall ensure that s/he is up to date with IRB approval.

- b. 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.
- 10. The Administrator of Planning and Research or designee and the MRAG, if necessary, must be provided the opportunity to comment on the final draft of research results prior to its publication at least two (2) weeks prior to submission.
 - a. The principal researcher shall submit a <u>MRAG Completed Research</u> form, to include requested documentation, to the Medical Program Director /MRAG and the Administrator of Planning and Research.
 - b. Comments are made, in writing, and sent to the researcher and academic advisor, where applicable.
 - c. The final draft is reviewed by the Administrator of Planning and Research or designee (non-medical) and/or the Medical Program Director (medical and behavioral) or designee.
- 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 Administrator of Planning and Research or designee at least two (2) weeks prior to submission for publication, presentation, and/or dissemination.

<u>NOTE</u>: The <u>MRAG Completed Research form</u> must be included with the draft and/or final submission.

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