WISCONSIN DEPARTMENT OF CORRECTIONS
EXECUTIVE DIRECTIVE

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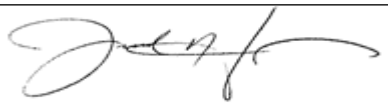
Secretary Approval:	

AUTHORITY

The Secretary of the Department of Corrections (DOC), as the head of a principal administrative agency within the executive branch of Wisconsin state government, has the power and duty to issue an executive directive to plan, direct, coordinate and execute the functions vested in the agency in carrying out programs and policies within the limits established by the legislature under Wis. Stat. Ch. 15.

BACKGROUND

The DOC supports and encourages research both in the field of criminal justice and in other areas related to the Department, as it seeks to advance the understanding, treatment, and rehabilitation of those individuals under its custody and care. To this end, the DOC shall assure that research carried out under its authority is held to a high standard and that persons who are subjects of research are protected. The purposes of this document are:

I. To describe how to apply for research at the DOC, the types of research allowed, the responsibilities of the DOC, the responsibilities of the Researcher(s), and the requirements for privacy and security.
II. To bridge the gap between research and criminal justice practice by encouraging research projects that will increase the understanding of PIOC populations, rehabilitative programming, correctional practices, and criminal justice issues more generally.

DEFINITIONS, ACRONYMS & REFERENCES

“Confidential Information” means communication, records, materials, and knowledge prohibited from disclosure or misuses by law, rule, order, regulation, DOC policy, or otherwise established by the Department.

“DAI” means the Division of Adult Institutions.

“Data” means information that the DOC’s Bureau of Technology Management stores, manages, or maintains. Data may pertain to “confidential information.”

“Data Request” means a forma request to the DOC for Data.

“DCC” means the Division of Community Corrections.

“DJC” means the Division of Juvenile Corrections.

“DOC-Operated Facility” means any building operated by the DOC (e.g. institutions, probation and parole offices, juvenile facilities, etc.).

“Employee” means any person employed by the DOC, including limited term employees, project employees, permanent or probationary employees, interns, students, volunteers, and contracted workers.

“External Research Projects” means research that is not conducted by DOC employees during the performance of their assigned duties. External research projects do not include Informational Requests or Survey Requests.

“Informed Consent” means a signed statement by a research participant indicating that they fully understand the research protocol, expectations for participation, risks and benefits associated with participation, and the option to freely discontinue participation at any time. This includes consent given by parents or guardians for those not able to provide informed consent.

“Institutional Review Board” or “IRB” means a committee (often associated with a university or college) that has been formally designated to approve and monitor research involving human subjects; the committee is intended to protect the rights and welfare of research subjects.

“Internal Research Projects” means Department-sponsored research that includes data collection with human subjects.

“Liaison” means an employee who coordinates communication between the Researcher and the DOC-operated Facility.

“Minimal Risk” means the probability and degree of harm or discomfort anticipated during the course of the research is no greater than the harm or discomfort encountered in the course of one's daily routine or during the performance of routine physical or psychological examinations.

"OOS" means Office of the Secretary.

"Participant" means an employee or PIOC being studied in a research project.

"PIOC" or "Person in our Care" means any person who is under the supervision of the DOC either in a correctional facility or in the community including but not limited to juveniles, inmate, probationers, parolees and person on extended supervision.

"Privacy Board" is a review body established to act upon request for a waiver or an alteration of the HIPAA authorization requirement under the HIPAA Privacy Rule for use in disclosures of protected health information (PHI) for a particular research study.

"Publication" refers to an effort to distribute research that has been reviewed by the RRC to a wider audience. "Wider audience" excludes the Researchers themselves, the members of the RRC, and other reviewers similar to the members of the RRC (such as members of an IRB board). Examples of publications include, but are not limited to, oral presentations, admissions for academic journals, and official reports.

"Research" is a procedure for systematic inquiry with the purpose of increasing knowledge or facilitating problem-solving.

"Research Activity" means a project, paper, or study designed primarily to produce new data, information, or understanding of corrections, criminal justice, management, or other issues relevant to the Department. Secondary data sources (existing Department data sets) may supplement such research.

"Research and Policy Unit" is a unit within the DOC responsible for leading research and evaluation efforts for the department and is under the authority of the OOS.

"Research Review Committee" or "RRC" is the DOC committee comprised of a group of individuals appointed by appropriate division leadership who are responsible for reviewing all research proposal of submitted to the Department. After review of the Research Requests, and seeking approval from affected DOC parties, the RRC will determine whether or not to approve the project. Research Requests will be reviewed to determine whether they are in compliance with guidelines dealing with the use of human subjects in research and with professional research standards.

"Research Request" is a request for research that uses DOC data; involves DOC participants; and/or will be conducted at a DOC-operated facility. Research Requests are subject to review by the RRC, and as such, are considered distinct from Data Requests, informational requests and Survey Requests.

"Researcher" means the primary person responsible for submitting the research proposal and overseeing completion of the project.

"Subject" at the same meeting as Participant.

"Survey Request" means a request for public information on the correctional population, employees of the Department, or Department policies and practices, which treats the Department itself as the participant, often along with other non-DOC correctional organizations.

"Working Days" means all days except Saturdays, Sundays, and legal holidays.

References:
Wis. Admin. Code DHS §92.08, Criminal Commitments
Wis. Stats. §51.30(4)(b)3, Records, State Alcohol, Drug Abuse, Developmental Disabilities and Mental Health Act
Wis. Stats. §51.61(1)(j) and (4), Patients' Rights
Wis. Stats. §§146.82(2)(a)6, Health Care Records, Miscellaneous Health Provisions
Wis. Stats. §252.15(2m)(b)1 HIV test results, Communicable Diseases
Wis. Stats. §938.78 Confidentiality of Records, Juvenile Justice Code
34 C.F.R. §99.31 (b)(2) Family Education Rights and Privacy Act (FERPA),
42 U.S.C.A. § 290dd-2(b)(2)b, Confidentiality of Records
42 C.F.R. Part 2, Confidentiality of Substance Use Disorder Patient Records
45 C.F.R Part 164.512(i), Health Insurance Portability and Accountability Act (HIPAA)
The Belmont Report, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
Executive Directive 75, Protection of Confidential Information
Standards for Health Services in Prisons, National Commission on Correctional Health Care

SCOPE

This policy applies to persons who wish to conduct research or evaluate data regarding human subjects. Human subjects include PIOC and employees. The scope of this policy includes external and internal research projects. Informational requests, survey requests and data requests for aggregate data are outside of the scope of this policy.

POLICY

The purpose of this policy is to establish guidelines that govern voluntary participation by employees and/or those under the care and custody of the Department.

The Department shall encourage cooperation between employees and Researchers in assisting with research design, data collection, and publication. Research activities using generally excepted research methods standards may contribute to correctional knowledge, to more efficient and effective facility operations, conservation of resources, benefits to current or future PIOC, and increased public safety.

Researchers are responsible for ensuring that the protocols of their proposed research comply with applicable federal and state laws, case law, and DOC policies and procedures. Researchers shall comply with all laws in effect at the time of the submission of a proposal. The law that provides the most stringent protection of privacy rights shall be been the controlling law with respect to each type of information. Researchers should consult with legal counsel as needed. Medical research on human subjects, including research on substance use disorders, will be reviewed with additional scrutiny, as outlined in Section VI, subsection F of this policy.

Researchers are responsible for costs incurred by special computing software, special equipment, employee resources, or any other required resources. If the Department covers any of the above costs, the Researchers may be required to reimburse the Department for expenses incurred. Such expenses can be waived by the Department.

In order to ensure the rights and interests of participants, all research efforts will follow the procedures outlined in this document, DOC policies, professional and scientific ethics, and comply with state and federal guidelines. Research activity cannot begin until written approval is acquired from the RRC. Researchers may not compensate participants for their participation unless specifically authorized by the RRC.

PROCEDURE

I. Procedure for Informed Consent to Participate in Research and Authorizations to Disclose Confidentiality

A. As human subjects of research, participants have a right to expect that confidential information gathered about them for a particular study will not be divulged in a manner that identifies any individual. The expectation of confidentiality extends not only to the procedures by which the research is carried out and to the published findings of the research, but also to the non-research related communications of the Researcher.

B. All proposals to conduct research that involve human subjects or that require information about human subjects must address the issues of privacy and confidentiality in the research protocol. The privacy of

research participants shall be respected. The RRC will review the protocol to ensure that the research will not directly or inadvertently result in disclosure of confidential information.

C. All research materials will be maintained by the Researcher for a minimum of five years. When materials are destroyed, they must be destroyed confidentially.

D. The Researcher must obtain written informed consent from participants before beginning research, unless granted an exemption from this by the RRC.

E. Researchers may not provide compensation or other rewards to participants for their participation in research, unless an exception is granted by the RRC.

F. When appropriate, employees may be informed of a PIOC inclusion in research activities.

When informed consent is required, it shall include all of the following elements in writing:

1. A brief statement of the research purpose.
2. An explanation of the research procedures.
3. A description of the potential discomforts and risks, as well as an explanation as to how those discomforts and risks will be addressed.
4. A description of the potential benefits to the participant or others.
5. A disclosure of all alternative procedures.
6. Contact information for research personnel responsible for answering questions and concerns.
7. A written statement that the participant may withdraw consent at any time or discontinue participation at any time without penalty. Procedures for withdrawal should be noted, as should the circumstances under which Researchers may terminate the participant's participation without the participant's consent.
8. A statement that any information disclosed to the Researcher will not be disclosed to the Department, except where the Researcher has knowledge, information or suspicion that the participant has experienced sexual abuse or sexual harassment during confinement, is a threat to their own safety, the health or safety of another person, or to the security or orderly operation of any DOC-operated facility, especially where a participant has expressed an intention to harm self or others.
9. A statement regarding the confidentiality of records/data, how that confidentiality will be maintained and the time period during which consent is effective.
10. A space for the signature of the individual whose records are being disclosed as well as the individual/organization to which the disclosure is made.
11. If the Researcher wants to quote participants in any manner, separate authorization is required by an additional space for signatures and date. Confidentiality and privacy must be respected as is appropriate for the participants' interest.

G. Standard procedure for research involving review, collection, or creation of individually identifiable protected health information requires that the participant sign an Authorization for the Use and Disclosure of Protected Health Information (DOC-1163A) authorizing the DOC to disclose the protected health information to the Researcher. The HIPAA/Privacy Officer shall review all research proposals that involve the review, collection, or creation of protected health information, and then consult with the Office of Legal Counsel as needed.

H. For a person under the age of 18 participation in a research project requires the informed consent of that person’s parent(s) or legal guardian(s).

II. Procedure for Requests

A. Researchers must complete the Research Request Application, DOC-1198, and submit the form electronically to DOCResearchRequest@wisconsin.gov.

B. Researchers may be required to undergo fingerprinting and/or a background check.

C. Employees conducting research for reasons outside of normal work duties must complete the Research Request Application above along with the Supervisor Consent for DOC Employee Researchers, DOC-138A. Employees shall submit a DOC-138A form which indicates that such research shall not be conducted during regular work hours, unless specifically authorized by the RRC and relevant supervising authorities of the employee. Employees are not permitted to conduct internal research projects without authorization.

D. Individuals submitting a research request for academic purposes (for example, a class or term paper, an internship paper, a dissertation, or a thesis), must be accompanied by their University's IRB approval. If IRB approval cannot be granted until after the RRC has approved the research, the RRC may grant conditional

approval, stating that the research must not begin until official IRB approval has been received by the Department.

E. All research proposals submitted by students (undergraduate or graduate level) must have a research advisor's signature on the Research Project Agreement, DOC-138, indicating both of the following: (a) the student's proposal has been reviewed and (b) the quality of the submission meets the college or university standards for quality and soundness of design. The student's research advisor's contact information must be included in Part IV: Description of Project Employees.

F. The Department will not approve any research requests submitted by PIOC under the custody or supervision of the Department requesting permission to conduct research, as defined in this Executive Directive.

G. The request must be submitted electronically to the Research Review Committee at DOCResearchRequest@wisconsin.gov.

H. A written response to acknowledge receipt of the research request materials will be made to the requestor within three working days of the receipt of the request. The notification shall provide an anticipated date that the RRC will review the request.

I. Projects submitted by staff members conducted in collaboration with a person affiliated with a research institution (such as a university) require a letter indicating the completion of an IRB review of that same project. This may be either IRB approval or an exemption granted by RRC to the requirement of an IRB review.

III. Procedure for Review

A. The RRC shall review all research proposals and determine whether or not to approve the project. Research proposals will only be reviewed if they offer a clear and complete explanation of the objectives of the research; its estimated impact; relation to previous research; and description of the methods, plan for analysis, and expected outcomes of the research. The RRC will automatically recommend that a proposal be denied under the following conditions:
   1. The research had already begun prior to DOC approval.
   2. The research requires excessive resources from the Department.

B. Research requests will be prioritized based on their alignment with the DOC's mission and strategical goals; their relevance to current legislation and legal mandates; and the availability of resources to support the requests. Research requests may be denied if they are not deemed a priority by the DOC.

C. Research requests shall be reviewed using the following criteria:

   1. Statutory or legislative authority to conduct the research.
   2. Statutory or regulatory authority to acquire or access the requested information.
   3. Study justification.
   4. Appropriateness of study design to answer research question(s).
   5. Protection of human subjects.
   6. Security and privacy standards for DOC confidential data, including personal information as defined by Executive Directive 75.
   7. Need and availability of Department resources.
   8. Potential adverse impact on the security and safety of the Department, its facilities, and employees.
   9. Voluntary participation by participants.

D. The RRC may function as a privacy board for purposes of HIPAA regulations under 45 CFR s. 164.512(i).

IV. Decision Making Process

A. Requests received less than one week prior to the next RRC meeting will not be reviewed until the following meeting.

B. The appropriate division representative will share materials pertaining to the request with the affected division for their review and recommendation.

C. Research requests involving disclosure of DOC Confidential information shall be reviewed by the DOC HIPAA/Privacy Officer for issues of privacy and confidentiality.

D. The RRC will review the proposal, delineate the pros and cons of the request, and then determine whether or not to approve the project.

E. Once items 2 through 4 of this section have been completed, the Researcher will be notified.

F. The Department reserves the right to deny any new proposals or terminate any ongoing research.

G. If the RRC has denied the project, or determines a continuing project must cease, the Chair of the RRC may give the Researcher an opportunity to address the reasons for denial or cessation, and the Researcher may submit a revised proposal.

H. The Department may impose conditions on the proposed research design or methodology to address concerns such as resources, security, or confidentiality issues. In the event that conditions are imposed, including the execution of a Memorandum of Understanding (MOU) between the DOC and the research requestor(s), the Department shall notify the Researcher of the conditions in the research approval notification.

I. A research project, with or without revisions (including changes to the Researcher), will no longer be reviewed if previously denied three or more times.

V. Expedited Review

The RRC may review a request on an expedited basis if one of the following applies: (a) the request is for an extension of an existing project; (b) the request has been previously approved by the RRC; or (c) the request is deemed by the RRC to not require a full review. If approved for an expedited review, the Researcher is not required to complete a formal research application. The Researcher must still provide a brief overview of their project, their proposed methods, and a reasonable justification for seeking an expedited review. An example of a proposal which may be reviewed under this provision is interviewing or surveying PIOC that had already been a part of an ongoing longitudinal research study.

VI. Continuing Review

A. Researchers must submit progress updates every six months until the completion of the project or more frequently as requested.

B. Any changes to the research request or protocols must be approved in writing by the RRC prior to implementation.

VII. Biomedical, behavioral, and other medical research using PIOC as participants must be consistent with established ethical, medical, legal, and regulatory standards for human research. The Researcher must demonstrate awareness of and adhere to associated federal and state statutes as they pertain to the extra protections for such research, in regards to protection of human subjects, and to federal compliance as it relates to both HIPAA and substance use disorder patient records.

VIII. Research activities shall commence within three months of the approval date. If research activities do not commence within three months, the RRC may require the Researcher to resubmit the request for re-approval with an explanation for the delay.

IX. A liaison may be assigned to assist the Researcher at the research location. The liaison shall serve as a resource regarding DOC policy and procedures and aid in compliance with those policies and procedures to maintain integrity throughout the study period.

X. Upon completion of the project, the Researcher is required to submit a copy of the final report to the RRC. Research participants may also request additional copies of the final report from the Researcher.

XI. If the Researcher intends to release their research as a Publication, they must submit the Publication to the RRC at least 30 days prior to submission or distribution of the Publication. The RRC will review it for accuracy and

integrity, and may recommend revisions prior to its distribution. The RRC may deny any request to distribute a Publication at their discretion.

XII. If, in the context of a project that requires RRC approval, a Researcher has received or collected data that may identify the DOC's staff or specific PIOC, the Researcher must receive approval by the RRC before they publish their data in any potentially publicly-facing capacity. This applies to any reason for publication. The RRC may deny requests to publish data at their discretion.

XIII. If a person that was a participant in a research project becomes incarcerated with the DOC, and all of the following conditions are true, that person must obtain approval from the RRC to continue participating while incarcerated:

A. The participant has given informed consent to participate.

B. The project has or has not been approved by the RRC prior to its implementation.

C. The project began while the person was in the community prior to the person being incarcerated.

XIV. The RRC will consider prior participation in such projects that have a direct health or therapeutic benefit to the participant with priority. If approval is not gained, the researcher will not continue research with that participant.

RESPONSIBILITY

Research Review Committee

I. The RRC consists of no fewer than five people. Each Division Administrator shall appoint a representative to the committee. An employee from the Research and Policy Unit will serve as the committee chairperson. Additional representatives may be appointed as deemed appropriate by the Director of Research and Policy.

II. Members of the RRC should have background and experience in a field of human research and/or an understanding of correctional operations.

III. If a member of the RRC submits a research request, they may not have direct or indirect involvement with the review of the research proposal.

IV. The RRC will meet as necessary to provide reasonable responsiveness to research applications and review