DIVISION OF ADULT INSTITUTIONS **POLICY AND PROCEDURES**	**DAI Policy #:** 500.10.34	**Page** 1 of 8
	Original Effective Date: 10/28/13	**New Effective Date:** 08/31/20
	Supersedes: 500.10.34	**Dated:** 11/03/14
	Administrator's Approval: Makda Fessahaye, Administrator	
	Required Posting or Restricted: [X] **Inmate** [X] **All Staff** [ ] **Restricted**	
Chapter: 500 Health Services		
Subject: Medical and Other Research		

POLICY

The Division of Adult Institutions shall ensure that biomedical, behavioral, or other research using patients as subjects is consistent with established ethical, medical, legal, and regulatory standard for human research.

REFERENCES

Standards for Health Care in Prisons, National Commission on Correctional Health Care, 2018, P-G-06 – Medical and Other Research
Executive Directive 36 – Human Subject Research Request Process and Procedure
Wisconsin Statute s. 302.38- Medical Care of Prisoners
Wisconsin Statute. s. 302.385- Correctional Institution Health Care
Wisconsin Statute s. 302.386- Medical and Dental Services for Prisoners and Forensic Patients

DEFINITIONS, ACRONYMS AND FORMS

DOC – Department of Corrections

DOC-138 – Research Project Agreement

DOC-138A – Supervisor Consent for DOC Employee Researchers

DOC-1098D – Application Supplement – Conviction Record

DOC-1163A – Authorization for the Use and Disclosure of Protected Health Information (PHI)

DOC-1198 – Researcher's Request for Confidential Records or Human Subjects Research

HIPAA – Health Insurance Portability and Accountability Act

Research Review Committee (RRC) – A DOC committee comprised of a group of individuals appointed by appropriate division leadership who are responsible for reviewing all research proposals 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.

PROCEDURE

I. General Guidelines

A. The DOC shall encourage cooperation between employees and research personnel in establishing research priorities and assisting with design, experimental design, data collection and assessment.

B. Research activities using generally accepted research methods and standards may contribute to correctional knowledge and thereby, to more efficient and effective facility operations, conservation of resources, benefit to current or future patients and increased public safety.

C. Researchers are responsible to ensure their protocols for proposed research comply with applicable federal and state law, case law and DOC policies and procedures.

D. Researchers shall comply with all laws in effect at the time of the submission of a proposal.

E. Experimental medical research including pharmaceutical or cosmetic testing is prohibited.

F. Researchers requiring specific computer programming, employee resources, or equipment shall reimburse the DOC for expense incurred. Such expenses may be waived by the Secretary.

G. All research efforts shall adhere to professional and scientific ethics and with state and federal guidelines in order to ensure their rights and interests.

H. Research activity shall not begin until written approval is obtained from the DOC's Research Review Committee.

I. Researchers may not compensate individuals for participation in research unless specifically authorized by the RRC.

II. Requests for Research Approval

A. Researchers shall complete the following forms:
   1. DOC-1198 – Researcher's Request for Confidential Records or Human Subjects Research.
   2. DOC-138 – Research Project Agreement.

B. The request shall be submitted electronically to the RRC at: DOCResearchRequest@wisconsin.gov.

C. DOC employees are not permitted to conduct research under this policy without authorization.

D. In addition to the forms listed above, DOC employees conducting research for reasons outside of normal work duties shall complete a DOC-138A – Supervisor Consent for DOC Employee Researchers which indicates the research shall not be conducted during regular work hours.

E. Students submitting a research request for academic purposes are required to have a research advisor review and sign the DOC-138, Research Project Agreement. The student's academic advisor's contact information shall be provided in Section IV. Description of Project Staff on the DOC-1198.

F. The DOC shall not approve any research requests submitted by patients, offenders or youth under the custody or supervision of the DOC in any state operated facility or community corrections office.

G. A written response acknowledging the receipt of the research request materials shall be made to the requestor within three working days of the request. The response shall also include an anticipated day the RRC will review the request.

III. Review of Research Requests

A. The RRC shall review all research proposals and determine whether or not to approve the project.

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

C. The RRC will prioritize research requests 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.

D. 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 patients.
   6. Security and privacy standards for DOC confidential data, including personal information as defined by Executive Directive 75.
   7. Needs and availability of DOC resources.
   8. Potential adverse impact on the security and safety of the DOC, its facilities and employees.
   9. Voluntary participation by patients.

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 shall 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 Privacy Officer and/or DOC HIPAA Compliance 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 B through D 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.

V. Expedited Reviews

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 offenders 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.

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

D. 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.

E. 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.

F. 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.

VII. Informed Consent to Participate in Research and Authorization to Disclose Confidentiality

A. Patients participating in research have the right to expect that confidential information gathered about them for a particular study shall 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 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 patients or that require information about patients shall address the issues of privacy and confidentiality in the research protocol.
   1. The privacy of participants shall be respected.
   2. The RRC shall review the protocol to ensure that the research will not directly or inadvertently result in the disclosure of confidential information.

C. All research materials shall 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 by the RRC.

E. When appropriate, DOC employees may be informed of a patient's inclusion in research activities.

F. An informed consent shall contain all of the following elements:
   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 these discomforts and risks shall be addressed.
   4. A description of the potential benefit to the subjects or to others.
   5. A disclosure of all the alternative procedures.
   6. Contact information for research personnel responsible for answering questions and concerns.
   7. A written statement that the patient 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 patient's participation without the participant's consent.
   8. A statement that any information disclosed to the researcher shall not be disclosed to the DOC; 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 shall 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 patient participant sign a DOC-1163A (Authorization for the Use and Disclosure of Protected Health Information (PHI)) authorizing the DOC to disclose protected health information to the researcher. The HIPAA Compliance Officer, or Office of Legal Counsel, shall review all research proposals that involve the review, collection or creation of protected health information.

VIII. RRC

A. The RRC consists of no fewer than five people.
   1. Each Division Administrator shall appoint a representative to the committee.
   2. An employee from the Research and Policy Unit shall serve as the committee chairperson. Additional representatives may be appointed as deemed appropriate by the Director of Research and Policy.
   3. Members of the RRC should have a background and experience in a field of human research and/or an understanding of correctional operations.

B. 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.

C. The RRC shall meet as necessary to provide reasonable responsiveness to research applications and reviews.

IX. Continuation of Community Research Upon Incarceration

A. The patient, in consultation with the community researcher, shall establish and implement a withdrawal from the protocol without harm to the patient.

B. The patient and researcher shall obtain a waiver from the DOC RRC to continue the research within the DOC (only when informed consent was obtained prior to prison incarceration) if the research has potential therapeutic benefit.

Bureau of Health Services: Michael Rivers **Date Signed:** 8/31/20
Michael Rivers, Director of Administration

Paul Bekx **Date Signed:** 8/31/20
Paul Bekx, MD, Medical Director

Mary Muse **Date Signed:** 8/29/20
Mary Muse, Nursing Director

Administrator's Approval: _____ **Date Signed:** 08/31/20
Makda Fessahaye, Administrator

DIVISION OF ADULT INSTITUTIONS FACILITY IMPLEMENTATION PROCEDURES

Facility: Name		
Original Effective Date:	**DAI Policy Number:** 500.10.34	**Page** 8 of 8
New Effective Date: 00/00/00	**Supersedes Number:**	**Dated:**
Chapter: 500 Heath Services		
Subject: Medical and Other Research		
Will Implement ☐ As written ☐ With below procedures for facility implementation		
Warden's/Center Superintendent's Approval:		

REFERENCES

DEFINITIONS, ACRONYMS AND FORMS

FACILITY PROCEDURE

I.

A.

B.

1.

2.

a.

b.

c.

3.

C.

II.

III.

RESPONSIBILITY

I. Staff

II. Inmate

III. Other