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:** 11/03/14
	Supersedes: 500.10.34	**Dated:** 10/28/13
	Administrator's Approval: Jim Schwochert, Administrator	
	Last Reviewed, No Changes: 03/15/16	
	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 support and encourage research in the field of criminal justice and other areas related to the understanding, treatment and rehabilitation of those individuals under the custody and care of the Department of Corrections. The Department of Corrections shall ensure the protection of the inmate patients participating in research that is consistent with the biomedical, behavioral and established ethical, medical, legal and regulatory standards for human research.

REFERENCES

Standards for Health Care in Prisons, National Commission on Correctional Health Care, 2014, P-I-06 – Medical and Other Research
Executive Directive 36 – Human Subject Research Request Process and Procedure

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 responsible for reviewing all unsolicited research proposals submitted to the DOC to determine compliance with guidelines dealing with the use of human subjects in research and with professional research standards. Members are appointed by the appropriate division leadership.

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 inmates 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 on an inmate patient 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 the rights and interests of inmate patients.

H. Research activity shall not begin until written approval is obtained from the DOC's Research and Policy Unit.

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.
   3. DOC-1098D – Application Supplement – Conviction Record.

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 collected during regular work hours.

E. Students submitting a research request for academic purposes are required to have their academic advisor review and sign a DOC-1198 – Researcher's Request for Confidential Records or Human Subjects Research. The 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 inmates, 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 recommend whether they proceed for further review.

B. If the RRC recommends that a proposal does not proceed, the proposal shall be referred to the leadership of the Research and Policy Unit for final decision.

C. The RRC shall only recommend for further consideration proposals which relate to DOC policies, facilities, programing, and management or those which enhance the literature related to correctional practices.

D. Research requests shall be reviewed using the following criteria:
1. Statutory or legislative authority to conduct the research.
2. Study justification.
3. Methodological rigor.
4. Protection of inmate patients.
5. Security of confidential data including personal information.
6. Needs and availability of DOC resources.
7. Potential adverse impact on the security and safety of the DOC, its facilities and employees.
8. Voluntary participation by inmate patients.

9. The research proposal offers a clear and complete discussion of the objectives, significance, previous research, methods, analysis and expected outcomes.

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 facility, program and employees for their review and recommendation.

C. If the recommendation is for denial of the requests, the RRC shall forward their recommendation to the Research and Policy Unit.

D. If a request is denied, the Research and Policy Unit may give a researcher the opportunity to address the reasons for denial and submit a revised proposal.

E. If the recommendation is for approval, the RRC shall continue its review of the request. The RRC shall then forward the recommendation to the Research and Policy Unit to make the final decision to approve or deny the request.

F. The DOC reserves the right to deny proposals that are poorly constructed or inadequately articulated, or that raise questions about the qualifications of the researcher. Academic preparation and previous research background shall serve as indicators of researcher qualifications.

G. The DOC may impose conditions on the proposed research design or methodology to address concerns, including resources, security, or confidentiality issues. If conditions are imposed the DOC shall notify the researcher of the conditions in the research approval notification.

H. All research proposals submitted by students must have a research advisor's signature indicating both of the following:
   1. They have reviewed the student's proposal.
   2. They agree that the quality of the submission meets both DOC standards and the college or university standards for quality and soundness of design.
   3. Students are required to demonstrate that they have approval from their school's Institutional Review Board. The RRC may provide tentative approval until confirmation of the Institutional Review Board approval is received.

I. Expedited Reviews
   1. An expedited review may occur if the request is for an extension of an existing project.
   2. An expedited review may occur if the request has been previously approved by the DOC.
   3. An expedited review may occur if the request does not require a full review**.**

J. Continuing Review
   1. The RRC shall review the progress of all research every six months or more frequently as needed.
   2. Any changes to research requests or protocols shall be approved in writing by the RRC prior to implementation.
   3. All researchers shall be contacted by the RRC chairperson every six months during the duration of the approved research to obtain an informational update regarding the progress of research. A letter outlining what the update shall entail shall accompany all letters of approval.

K. 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.

L. A site liaison may be assigned to assist the researcher regarding DOC policy and procedures and aid in compliance with those policies and procedures to maintain integrity throughout the study period.

M. The RRC may suspend or terminate a research project at any time. The RRC shall notify the researcher in writing of its decision.

N. Upon completion of the project, the researcher is required to submit to the DOC a copy of the final report and a one page executive summary or scientific abstract of findings. Inmate patients may request a copy of the final report from the researcher.

O. The researcher shall submit any paper for publication to the DOC at least 30 days prior to submission for publication. The DOC shall review the paper for accuracy and integrity, and may request revisions to the report prior to final publication.

P. The researcher shall send a final copy to the Research and Policy Unit.

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

A. Inmate patients participating in research have the right to expect that confidential information specific to 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 inmate patients or that require information about inmate patients shall address the issue of privacy and confidentiality in the research protocol.
   1. The privacy of inmate patient participants shall be respected.
   2. The RRC shall review the protocol to ensure that the research shall not directly or inadvertently result in the disclosure of confidential information.

C. All research material shall be maintained by the researcher for a minimum of five years, after which time the materials shall be destroyed by deleting, shredding, or burning.

D. The researcher must obtain written informed consent from inmate patient participants before beginning research, unless granted an exemption by an Institutional Review Board and the RRC. Researchers are advised to secure informed consent even where RRC review indicates no serious potential from harm for the research proposal.

E. When appropriate, DOC employees may be informed of an inmate 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 inmate 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 inmate patient's participation without consent.
   8. A statement that any information disclosed to the researcher shall not be disclosed to the DOC; except where the researcher believes the inmate patient participant is a threat to their own safety, the health or safety of others or to the secure operation of any state correctional facility.
   9. A statement regarding the confidentiality of records/data and how that confidentiality shall be maintained.
   10. A space for signatures and date.

G. Research involving review, collection or creation of individually identifiable protected health information requires that the inmate 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.

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

B. No member of the RRC may have direct or indirect involvement with the research being reviewed.

C. No additional compensation is provided for membership on the RRC.

D. The RRC shall meet quarterly or as necessary to provide reasonable responsiveness to research applications and reviews. The RRC shall make recommendations to the Research and Policy Unit.

VII. Continuation of Community Research Upon Incarceration

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

B. The inmate patient participant 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: _____Date Signed: _____
James Greer, Director

_____Date Signed: _____
Ryan Holzmacher, MD, Medical Director

_____Date Signed: _____
Mary Muse, Nursing Director

Administrator's Approval: _____Date Signed:_____
Jim Schwochert, 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 Health 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