

<p style="text-align: center;">WISCONSIN DEPARTMENT OF CORRECTIONS</p>  <p style="text-align: center;">EXECUTIVE DIRECTIVES</p> <p>3099 E. Washington Ave. P.O. Box 7925 Madison, WI 53707-7925 (608) 240-5000</p>	DOC Library # 200.400.0036	
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EXECUTIVE DIRECTIVE # 36

Subject Human Subject Research Request Process and Procedure

I. Authority

Each state agency has the authority to set policies to carry out its responsibilities and charge. Wis. Stats. §15.0001(2)(a).

Wis. Stats. Ch. 301, Corrections

Wis. Stats Ch. 302, Prisons; State, County and Municipal

Wis. Stats Ch. 304, Paroles & Pardons

Wis. Stats. §51.30, Records, State Alcohol, Drug Abuse, Developmental Disabilities and Mental Health Act

Wis. Stats. §118.125, Pupil Records, General School Operations

Wis. Stats. §§146.81-82, Health Care Records, Miscellaneous Health Provisions

Wis. Stats. §252.15, HIV test results, Communicable Diseases

Wis. Stats. §938.78, Confidentiality of Records, Juvenile Justice Code

Wis. Administrative Code Ch. DHS 92, Confidentiality of Treatment Records

34 Code of Federal Regulations (C.F.R.) Part 99 (FERPA), Family Education Rights and Privacy Act

42 C.F.R. Part 2, Alcohol and other drug abuse information

45 C.F.R. Part 164, Health Insurance Portability and Accountability Act (HIPAA)

45 C.F.R. Part 46, Protection of Human Subjects

The Belmont Report, National Commission for the Protection of Human Subjects of

Biomedical and Behavioral Research
Executive Directive 16, Fraternalization Policy

II. Background

The Department of Corrections supports and encourages 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. To this end, the DOC shall assure quality research and protect persons who are subjects of research. The purposes of this document are:

- To describe how to apply for research approval, the types of research allowed, the responsibilities of the DOC and of researchers, and the requirements of privacy and security; and
- To bridge the gap between research and practice by encouraging research projects that will increase the understanding of offender populations and corrections programming specifically and criminal justice issues more generally.

III. Definitions & Acronyms

“Confidential Data” means individually identifying information. Examples include health care records (medical, dental, mental health and alcohol and drug abuse), pre-sentence investigations, psychological reports, conduct reports, and probation and parole reports.

“DAI” means the Division of Adult Institutions

“Data Request” means a formal request to the Department for data stored and maintained by the Bureau of Technology Management (BTM) using a DOC-255 form.

“DCC” means the Division of Community Corrections.

“DJC” means the Division of Juvenile Corrections.

“DOC” or “Department” means the Department of Corrections.

“Employee” means a person employed by the DOC in a classified or unclassified position, volunteers, or contractors.

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

“Informational Request” means a request for information concerning inmates, offenders, youth, employees, operations, policies, or programs of the Department. An informational request is a request for a specific piece of information. These include Data Requests.

“Informational Survey” means a data collection tool used to gather public information on the correctional population or employees of the Department.

“Informed Consent” means a signed statement by a research participant indicating that he or she fully understands the research protocol, expectations for participation, risks and benefits associated with participation, and the option to freely discontinue participation at any time.

“Inmate” means an offender who is currently confined in a prison as defined under s. 302.01, Wis. Statutes, or a youth committed to a juvenile correctional institution under s. 938.02 (10p), Wis. Statutes.

“Institutional Review Board (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 projects and those conducted through the normal responsibilities of daily work.

“Liaison” means an employee who coordinates communication between the researcher and the site.

“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.

“Offender” means any individual, regardless of age, who is or has been involuntarily confined or detained in a DOC institution or center, under probation or parole, extended supervision, or under intensive sanctions supervision. The term encompasses individuals (a) sentenced to such an institution under a criminal or civil statute, (b) detained in other facilities by virtue of statute or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, (c) detained pending arraignment, trial, or sentencing, or (d) under field supervision.

“OOS” means Office of the Secretary.

“Participant” has the same meaning as Subject.

“Research” is a procedure for systematic inquiry with the purpose of increasing knowledge or to facilitating problem solving. Research is distinct from Informational Requests and Informational Surveys.

“Research Review Committee” or “RRC” means the DOC committee which is responsible for reviewing all unsolicited research proposals submitted to the Department to determine compliance with guidelines dealing with the use of human subjects in research and with professional research standards. RRC members are appointed by the appropriate division leadership.

“Research Activities” means a project, paper, or study designed primarily to produce new data, information, or understanding of corrections, criminal justice, management, or other issues of relevance to the Department. Secondary data sources (existing Department datasets) may supplement such research.

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

“Site” means the location where the research project is going to be conducted.

“Subject” means an offender, inmate, or youth under the care and custody of the department or an employee being studied in a research project.

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

“Youth” means any individual, regardless of age, who is under the care and custody of the Division of Juvenile Corrections, either committed to a juvenile correctional facility or under supervision in the community.

IV. Scope

This policy applies to persons who wish to conduct human subjects research or evaluate data regarding human subjects including offenders, youth, and employees. The scope of this policy includes External Research Projects. Informational Requests or Survey Requests are outside of the scope of this policy.

V. Policy

The purpose of this policy is also to establish guidelines that govern voluntary participation by employees and those under the care and custody of the Department in non-medical, non-pharmaceutical, non-cosmetic research.

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

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 the controlling law with respect to each type of information. Researchers should consult with legal counsel as needed. Experimental medical research, including pharmaceutical or cosmetic testing, on a subject is prohibited.

Researchers requiring specific computer programming, employee resources, or equipment must reimburse the Department for expenses incurred. Such expenses can be waived by the Secretary.

All research efforts will follow the procedures outlined in this document and DOC policies and adhere to professional and scientific ethics and with state and federal guidelines in order to ensure the rights and interests of subjects. Research activity will not begin until written approval is acquired from the Department's Research and Policy Unit.

Researchers may not compensate subjects for their participation unless specifically authorized by the RRC.

VI. Procedure

A. Procedure for Requests.

1. Researchers must complete the following forms:
 - a. Research Request Application, DOC-1198.
 - b. Research Project Agreement, DOC-138.
 - c. Application Supplement-Conviction Record, DOC-1098 D.
2. The request should be submitted electronically to the Research Review Committee at DOCResearchRequest@wisconsin.gov
3. Employees conducting research for reasons outside of normal work duties must complete the forms above along with the DOC-138A. Employees shall submit a DOC-138A form which indicates that such research shall not be conducted during regular work hours; employees are not permitted to conduct research under this policy without authorization.
4. Students submitting a research request for academic purposes (for example, class or term paper, internship paper, dissertation, or thesis) are also required to have their academic advisor review and sign the DOC-1198. The academic advisor's contact information must be included in Part IV. Description of Project Employees.
5. The Department will not approve any research requests submitted by inmates, offenders, or youth under the custody or supervision of the Department requesting permission to conduct research in any state operated institution or community corrections office.
6. A written response to acknowledge receipt of the research request materials will be made to the requestor within three working days of receipt of the request. The notification shall provide an anticipated date that the RRC will review the request.

B. Procedure for Review

1. The RRC shall review all research proposals and recommend whether they
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proceed for further review. If the RRC recommends that a proposal does not proceed, the proposal will be referred to the leadership of the Research and Policy Unit for final decision. The RRC will only recommend for further consideration proposals which relate to Department policies, facilities, programming, and management or which enhance the literature related to correctional practices.

2. Research requests shall be reviewed using the following criteria:
 - a. Statutory or legislative authority to conduct the research.
 - b. Study justification.
 - c. Methodological rigor.
 - d. Protection of human subjects.
 - e. Security of confidential data, including personal information.
 - f. Need and availability of DOC resources.
 - g. Potential adverse impact on the security and safety of the Department, its facilities, and employees.
 - h. Voluntary participation by participants.
 - i. The research proposal offers a clear and complete discussion of the objectives, significance, previous research, methods, analysis, and expected outcomes.

C. Decision Making Process

1. Requests received less than one week prior to the next RRC meeting will not be reviewed until the following meeting.
2. The appropriate division representative will share materials pertaining to the request with the affected institution, program, and employees for their review and recommendation.
3. If the recommendation is for denial of the request, the RRC will take no further action and inform the leadership of the Research and Policy Unit.
4. If the recommendation is for approval, the RRC will continue its review of the request. The leadership of the Research and Policy Unit shall make the final decision to approve or deny the request.
5. If a request is denied, the leadership of the Research and Policy Unit may give a researcher an opportunity to address the reasons for denial and submit a revised proposal.

The Department 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.

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

All research proposals submitted by students (undergraduate or graduate level) must have a research advisor's signature indicating both of the following: (1) he or she has

reviewed the student's proposal and (2) he or she agrees that the quality of the submission meets both DOC standards and the college or university standards for quality and soundness of design. In addition, students are required to demonstrate that they have obtained approval from their school's IRB. The RRC may provide tentative approval until confirmation of the IRB approval is received.

D. Expedited Review

The Department may review a request on an expedited basis if one of the following applies: (1) the request is for an extension of an existing project; (2) the request has been previously approved by the Department; or (3) the request does not require a full review. An example of a proposal which may be reviewed under this provision includes interviewing or surveying offenders already enrolled in a longitudinal research study (related or unrelated to his or her DOC incarceration or supervision).

E. Continuing Review

1. The Research Review Committee will review the progress of all research every six months, or more frequently as needed.
2. Any changes to the research request or protocols must be approved in writing by the Research Review Committee prior to implementation.
3. All researchers will be contacted by the RRC chair every six months during the duration of the approved research to provide an informal update regarding the progress of the research. A letter outlining what the update will entail will accompany all letters of approval.

F. 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 resubmit the request for re-approval with an explanation for the delay.

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

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

I. Upon completion of the project, the researcher is required to submit to the Department a copy of the final report and a one-page executive summary or scientific abstract of findings. Participants may request from the researcher a copy of the final report.

J. The researcher shall submit any paper intended for publication to the Department at least 30 days prior to submission for publication. The Department will review the paper for accuracy and integrity, and may recommend revisions prior to publication. Following publication, the researcher shall send a copy to the leadership of the Research and Policy Unit.

VII. 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 Research Review Committee will review the protocol to ensure that the research will not directly or inadvertently result in the disclosure of confidential information.
 - C. All research materials will be maintained by the researcher for a minimum of five (5) years, after which time materials will be destroyed by deleting, shredding or burning.
 - D. The researcher must obtain written informed consent from participants before beginning research, unless granted an exemption from this by an Institutional Review Board (IRB). Researchers are advised to secure informed consent even where RRC review indicates no serious potential harm from the research proposal.
 - E. Researchers may not provide compensation or other rewards to participants for their participation in research, unless special permission is granted by the RRC.
 - F. When appropriate, employees may be informed of an offender's inclusion in research activities.
 - G. An Informed Consent shall include 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 those discomforts and risks will be addressed.
 - 4. A description of the potential benefits, to the subject or to 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 subject's participation without the subject's consent.
 - 8. A statement that any information disclosed to the researcher will not be disclosed
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to the Department, except where the researcher believes the participant is a threat to his or her own safety, the health or safety of another person, or to the security or orderly operation of any state correctional institution or community corrections site, especially where a participant has expressed an intention to harm self or others.

9. A statement regarding the confidentiality of records/data and how that confidentiality will be maintained.

10. A space for signatures and a date.

- H. 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 Compliance Officer, or Office of Legal Counsel, shall review all research proposals that involve the review, collection or creation of protected health information.

VIII. Research Review Committee (RRC)

- A. The Research Review Committee 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. Members of the RRC should have 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 will meet quarterly or as necessary to provide reasonable responsiveness to research applications and reviews. The RRC will make recommendations to the Research and Policy Unit.
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