



WYOMING DEPARTMENT OF CORRECTIONS

Policy and Procedure #1.401 Authorized Research Activities

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<p>Authority:</p> <p>Wyoming Statute(s): 6-4-203(b)(iii); 7-19-106(a)(v); 25-1-104; 25-1-105</p> <p>ACA Standard(s): 4-4108; 4-4109; 4-4110; 4-4111; 4-4112-R; 4-4113; 4-4402-R; 1-ABC-4E-49 2-CO-1F-09 through 1F-12; 2-CO-1F-13-R; 2-CO-1F-14;</p> <p>NCCHC Standard(s): 2-CO-1F-15 P-I-06</p>	<p>Effective Date: August 22, 2016</p> <p>Revision/Review History: 08/31/15 08/01/14 05/15/14 08/01/13 08/01/12 08/08/11</p> <hr/> <p>Summary of Revision/Review: Updates existing policy pursuant to annual review.</p>
<p>Cross Reference of Policy:</p>	<p>Supersedes Existing Policy : P&P #1.401, <i>Medical and Other Research Activities</i>, dated 8/1/12</p>
<p>Approved:</p> <p style="text-align: center;">R.O. Lampert 8-16-16</p> <hr style="width: 100%;"/> <p style="text-align: center;">Robert O. Lampert, Director Date</p>	

REFERENCE

1. ATTACHMENTS
 - A. WDOC Form #169, *Research Agreement*
 - B. WDOC Form #170, *Research Consent Form*

2. OTHER
 - A. 45 CFR 46: *Protection of Human Subjects*



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I. PURPOSE

- A. **Research.** The purpose of this policy and procedure is to establish uniform guidelines to govern research activities relevant to Wyoming Department of Corrections (WDOC) programs, services, and operations and voluntary offender participation in non-medical, non-pharmaceutical, and non-cosmetic research and to describe the research procedures.

II. POLICY

- A. **General Policy.** It is the policy of the WDOC to support and engage in research activities relevant to its correctional programs, services and operations. (ACA 4-4108, 2-CO-1F-10)
1. Research may be conducted internally by WDOC staff. WDOC shall also permit, encourage and use research conducted by outside professionals. (2-CO-1F-11)
 - i. The purpose of such research shall be to assist in planning or evaluation of operations, programs, and/or services.
 2. Offender or staff participation in non-medical, non-pharmaceutical, and non-cosmetic research programs shall be voluntary and shall be governed by this policy and procedure. (ACA 4-4113, 2-CO-1F-13-R)
 3. Internal research activities shall be approved by the Deputy Director and coordinated through the Research Manager. Chief Executive Officers (CEOs) shall also encourage and use research conducted by outside professionals when available, appropriate, and approved in accordance with this policy. (ACA 4-4109)

III. DEFINITIONS

- A. **Experimental Medical Research:** Systematic inquiry evaluation of new treatments in clinical trials and all other research that contributes to the development of new treatments.
- B. **Offender:** (*For this policy only.*) A person who has entered a plea of guilty or has been convicted of a misdemeanor or a felony and is committed to the custody or supervision of WDOC.



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- C. **Program Review:** A research activity that measures the effectiveness of a particular program in the achievement of an immediate objective.
- D. **System Review:** A research activity that , ensures the overall performance of the entire organization in achieving its goals and objectives.

IV. PROCEDURE

- A. **Internal Research Activities.** Research activities to be conducted by WDOC staff shall be submitted in writing to the Deputy Director for review and approval. The Research Manager shall be consulted regarding the ability to conduct the research and the research activity shall be coordinated through the Research Manager.
- B. **Application to Conduct Outside Research.** Every application to conduct research activities by an outside professional shall be directed to the Deputy Director and/or the appropriate Division Administrator and shall include:
 - 1. Title of study;
 - 2. Name, address, and telephone number of the principal researcher and all research staff;
 - 3. An endorsement by a recognized research organization (*e.g.*, university, college, private foundation, consulting firm, or public agency) that has a mandate to perform research, certifying that the research proposal is for valid scientific, educational, or other public purposes;
 - i. If Human Subjects Reviews have been conducted and approved through the requesting research organization, they shall be provided to the WDOC as part of the endorsement.
 - 4. A summary of the goals of the study and the justification for the research; and
 - 5. A detailed research design including:
 - i. The WDOC resources and staff that may be needed for the study;
 - ii. The sampling procedures for selecting offender records for the research as well as the criteria that will be used for sample selection;



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- iii. The procedures for data collection and copies of research instruments to be used including interview schedules, questionnaires, data collection forms, and tests; and
 - iv. Details of compensation, if any, to be paid.
- C. **Research Approval.** CEOs shall review all research projects prior to implementation to ensure that appropriate approval has been granted and to ensure that they conform to this policy. The following procedure shall be followed for review and approval on all research proposals and/or designs prior to their implementation. (ACA 4-4112-R, 2-CO-1F-12)
- 1. **Internal Research Activities.** Approval for research activities to be conducted by WDOC staff shall be determined by the Deputy Director. Requests for internal research shall be submitted to the Deputy Director with sufficient detail regarding the proposed research activity.
 - 2. **Outside Research Activities**
 - i. Two (2) copies of the application to conduct outside research shall be submitted to the Deputy Director and/or the appropriate Division Administrator.
 - a. If the study requires the direct involvement of offenders (*e.g.*, responding to interviews, completing questionnaires), the Deputy Director and/or the appropriate Division Administrator may ask a representative group of staff to review the application and submit a recommendation for approval or disapproval.
 - ii. The Deputy Director and/or the appropriate Division Administrator shall ensure that all researchers are informed of agency policy concerning research. A signed agreement shall be completed prior to initiation of the project. At a minimum, the researcher will be required to complete WDOC Form #169, *Research Agreement*. At the discretion of the Deputy Director, a written contract may also be required.
 - iii. The Deputy Director and/or the appropriate Division Administrator shall approve the plan for using and disseminating the research findings prior to the start of research, and shall review and comment on the final findings prior to actual dissemination.



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D. Prohibited Research. The use of offenders for medical, pharmaceutical, or cosmetic experiments is expressly prohibited. This does not preclude offender participation in clinical trials that are approved by WDOC and an institutional review board based on the offender’s need for a specific medical intervention. Any such research shall be in compliance with all state and federal guidelines. (ACA 4402-Revised, 1-ABC-4E-49, 2-CO-1F-14)

1. Prohibited experimental programs include aversive conditioning, psychosurgery, or cosmetic substances being tested prior to sale to the general public.
2. An individual’s treatment with a new medical procedure by his or her physician should be undertaken only after the offender has received a full explanation of the positive and negative features of the treatment and only with informed consent.
3. When inmates who are participants in a community-based research protocol are admitted to WDOC facilities, procedures provide for:
 - i. Continuation of participation; or
 - ii. Consultation with community researchers so that withdrawal from the research protocol is done without harming the health of the inmate.

E. Conduct of Approved Research

1. The conduct of research shall include compliance with professional and scientific ethics; medical, legal, and regulatory standards for human research; and all state and federal guidelines for the use and dissemination of research findings. (ACA 4-4111; NCCHC P-I-06)
 - i. Research shall conform to 45 CFR 46 for the protection of human subjects.
2. The researcher shall obtain signed consent from offenders and staff who are scheduled to participate in the research using WDOC Form #170, *Research Consent Form*.
3. A staff member shall be assigned to assist outside research personnel in facilitating the research, monitoring and evaluating the research project and paying particular attention to compliance with policies on confidentiality. Operational personnel shall assist research personnel in



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carrying out research and evaluations as directed by the appropriate CEO. (ACA 4-4110)

4. The principal researcher shall explain the study and its justification to all potential subjects.
 - i. A written summary, in non-technical language, shall be prepared to facilitate this explanation and a copy provided to each potential subject.
 - ii. It shall be made clear to all offenders that their participation in the research shall be purely voluntary and that their participation shall, in no way, affect the terms or length of their incarceration or supervision.
5. The principal researcher shall maintain adequate records to enable the Deputy Director and/or the appropriate Division Administrator to ascertain the status of the study at any time.
6. Any data collected during the course of research shall be used only in the manner described to the subject prior to his or her entry into the study or in a manner specifically permitted by the subject subsequently.
7. No employee of the WDOC shall receive compensation, remuneration, or payment of any kind from the researcher.
8. Appropriate confidentiality shall be maintained through the course of all research activities in accordance with WDOC policy and state and federal laws.
 - i. The specific details of bona fide research projects being conducted by WDOC are protected records pursuant to W.S. § 6-4-203(b)(iii).
 - ii. The privacy of participants will be maintained during all research. (2-CO-1F-15)
 - a. All documents, data compilations, reports, computer programs, photographs, and any other work provided to or produced in the course of research activities shall be kept confidential by the researcher unless written permission is granted by WDOC for its release.



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- ii. A distinction is made between system review and program review;
- iii. The Deputy Director and/or the appropriate Division Administrator shall approve the distribution of all agency research; and
- iv. Copies of all research findings shall be forwarded to the WDOC Director at least fifteen (15) days prior to the proposed distribution.

V. TRAINING POINTS

- A. What organizations/groups are eligible to conduct research at the WDOC?
- B. Name three (3) components of a detailed research design.
- C. Is medical, pharmaceutical or cosmetic research on offenders ever permitted?
- D. Describe the process of disseminating research.