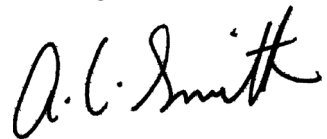




Department of
Rehabilitation & Correction

SUBJECT: Human Subjects Research Policy	PAGE <u> 1 </u> OF <u> 5 </u>
	NUMBER: 06-RES-02
RULE/CODE REFERENCE:	SUPERSEDES: 06-RES-02 dated 10/23/17
RELATED ACA STANDARDS: 4-4109 thru 4-4113, 4-4402M; 5-ACI-1F-14 thru 1F-18, 5-ACI-6C-09M	EFFECTIVE DATE: March 2, 2020
	APPROVED: 

I. AUTHORITY

Ohio Revised Code 5120.01 authorizes the Director of the Department of Rehabilitation and Correction, as the executive head of the department, to direct the total operations and management of the department by establishing procedures as set forth in this policy.

II. PURPOSE

The purpose of this policy is to establish the framework for the review and approval of proposals for research projects to be conducted within the Ohio Department of Rehabilitation and Correction (ODRC).

III. APPLICABILITY

This policy applies to all persons employed by the ODRC, all persons under contract to the ODRC, and to all persons not employed by or under contract with the ODRC who wish to conduct research within the ODRC.

IV. DEFINITIONS

Confidentiality - As human subjects of research, offenders have a right to expect that non-public information gathered about them for a particular study will not be divulged in a manner that identifies any individual offender and/or specific facts about that offender. Employees of the ODRC who are the subjects of research should expect the same confidentiality protections. The expectation of confidentiality applies not only to the procedures by which the research is carried out and to the published findings of the research, but also to non-research related communications of the researcher.

Human Subjects Research Review Committee (HSRRC) - A multi-disciplinary team, appointed by the Director or the Director's designee, created to review research studies conducted by individuals outside the ODRC (and, in some cases, by individuals or groups within the ODRC) to determine compliance with guidelines dealing with the use of human subjects in research and with professional research standards.

Offenders under Department of Rehabilitation and Correction Community Supervision - Includes parolees, those on post-release control, transitional control, and community control.

Research - Research is the careful and systematic study and investigation of a field of knowledge which is undertaken to discover or establish facts or principles, to determine the impact and/or effectiveness of practices, or to study the possible impact of change on a system.

V. POLICY

The Ohio Department of Rehabilitation and Correction (ODRC) encourages and uses research conducted by outside professionals. It is the policy of the ODRC to govern the conduct of research within the agency, including compliance with professional and scientific ethics and with state and federal guidelines.

VI. PROCEDURES

A. Research Review Process

1. All external and internal projects defined as research must be reviewed and approved by the HSRRC.
2. Research activities undertaken by ODRC employees or contract staff for the purpose of quality improvement, program monitoring, management audit, and/or state interagency collaborations with ODRC do not need the HSRRC review or approval, unless the research is also being used for a student project (i.e., course paper, master's thesis or doctoral dissertation), journal article, book, or other publication.
3. Any research project conducted using information collected directly from offenders, ODRC employees, or obtained from the ODRC concerning offenders, others under the jurisdiction of the ODRC, or employees of ODRC, must adhere to generally accepted standards of confidentiality of subjects' identities.
4. An Application for Review of Research Proposal (DRC1836) shall be submitted to the chair of the HSRRC for all proposed research. Each application shall be accompanied by a completed Research Proposal Approval (DRC1827).
5. During the pre-review process, the chair of the HSRRC will perform an informal review of the research application for general appropriateness prior to distribution to the HSRRC.
6. The HSRRC shall meet regularly to review research applications. All research applications shall be examined according to the following standards:
 - a. If the research involves the use of offenders under the jurisdiction of the ODRC as human subjects, the application must demonstrate a clear and reasonable nexus for using an offender population.
 - b. If the research involves the use of offenders or information about offenders, the application must meet appropriate standards for privacy, confidentiality, and the protection of the welfare of the offenders. For a research to garner HSRRC approval,

the proposal must address protection of privacy and confidentiality of subjects and include a clear data security plan.

- c. Projects that pose a significant physical or mental health risk to offenders will not be approved.
- d. Research projects which involve the use of offenders or employees of ODRC as human subjects or require information about offenders or employees of ODRC cannot be conducted by current or former offenders.
- e. Payment of any kind to incarcerated offenders, or their relatives or friends, for the offender's participation in research projects is not permitted. Payments to offenders on community supervision may be allowed with the approval of the HSRRC. Payment to employees for participation in research projects is not permitted.
- f. The cost of the project to the ODRC (i.e., staff time required to pull files for review, escort offenders, provide security for research personnel, or in other areas such as computer support) shall be considered in the decision to approve or disapprove the research application.
- g. Requests to continue research activities involving individuals who were human subjects of a research project prior to their incarceration or coming under the jurisdiction of the ODRC are sometimes received. These requests shall be considered by the HSRRC, particularly with respect to voluntary informed consent and payment to subjects.
- h. The HSRRC shall decide whether a research request constitutes "journalism" or "research." Requests constituting "journalism" can be approved by ODRC's Communications Office. Requests constituting "research" shall be referred to the HSRRC.
- i. All participation in research must be voluntary and informed regarding risk of harm, possible benefits, and other details of the proposed study. If the research subjects will be identified and this identity will be linked to the research data (e.g., surveys, records, testing scores), and/or the risks of participation are more than minimal, the researchers must create an informed consent form that participants must sign. Research projects which require only the anonymous completion of surveys and minimal risk of harm do not need voluntary, informed consent forms.
- j. Projects conducted by individuals with an academic affiliation (faculty or student) must be approved by the appropriate college or university Institutional Review Board (IRB) prior to final approval by the HSRRC. If the IRB needs approval from the ODRC prior to providing their own approval, the HSRRC may provide tentative approval. Internship evaluation projects determined to be IRB exempt by the student's college or university will only require the HSRRC approval.
- k. Project personnel are expected to have study-specific qualifications; that is, there is a presumption that project personnel have the substantive and methodological

knowledge to successfully complete the proposed study. Student projects must be supervised by an advisor with appropriate credentials to conduct the research.

- l. Individuals completing research related to internships at the ODRC will submit research and evaluation proposals to the HSRRC.
- m. Current and former employees of the ODRC may wish to utilize offenders or other employees as subjects in research studies they are completing as part of an educational training program or degree program. This is permitted, provided the following conditions are met:
 - i. The current or former employee is in good standing with ODRC at the time the research proposal is received by the HSRRC.
 - ii. A current employee of ODRC must agree to complete the research on their own personal time, and not while at, or engaged in, duties for their institution of employment.
 - iii. Current and former ODRC employees are encouraged to conduct the research at an institution other than the current or most recent institution of employment. Exceptions may be granted with the approval of the HSRRC.
 - iv. Current and former ODRC employees will not be granted any greater access to or privileges from ODRC institutions at which they are conducting research relative to any outside researcher conducting a study utilizing one or more ODRC institutions.
7. A project that is not approved may be returned to the researcher with suggestions from the HSRRC about how the project can be modified in order to secure the HSRRC approval. It is the sole responsibility of the researcher to follow up on HSRRC suggestions. A project that is rejected by the HSRRC cannot be resubmitted, and the researcher will be provided with written feedback on the reason(s) for rejection. The researcher is free to submit new proposals to the HSRRC at their convenience.
8. After the HSRRC approval is granted, the chair of the HSRRC shall send the documents relating to an approved research project to the appropriate managing officer or deputy director in which the proposed research will be conducted.
 - a. They will decide on the feasibility of conducting the approved research in the designated facility or field office, ensure that the research conforms to the policies of the parent agency, and decide as to whether approval shall be granted.
 - b. For proposed research that will be conducted in many institutions/APA regions, the documents pertaining to an approved project shall be sent to the managing officer of prisons for approval.
 - c. The Operation Support Center (OSC) designee is the last party to review and approve the research.

9. Researchers both outside and within the ODRC who receive the HSRRC approval to conduct a research project in the ODRC are required to furnish a copy of the project final report to the ODRC through the HSRRC prior to publication or presentation.
10. The research should be conducted within a reasonable timeframe, as determined by the principal investigator of the research in collaboration with the HSRRC. The HSRRC reserves the right to terminate a project if it exceeds a reasonable timeframe.
11. The applicant may request an endorsement letter from ODRC to meet requirements from a funding source or university's IRB. However, the research proposal will undergo a full review and must receive all necessary approvals before the applicant is authorized to conduct the research study.
12. A researcher cannot use data for any project other than the current project for which they have received the HSRRC approval.

B. Proscription of Medical, Pharmaceutical, and Cosmetic Research

1. Participation of offenders in medical or pharmaceutical research purely for experimental purposes is not permitted.
2. In rare and exigent circumstances, the Office of Correctional Health Care (OCHC) may authorize use of an experimental treatment for an offender on a case-by-case basis, utilizing appropriate institutional reporting and documentation of the case.

Related Department Forms:

Research Proposal Approval form	DRC1827
Review of Research Proposal form	DRC1836