STATE OF OHIO

DEPARTMENT OF REHABILITATION AND CORRECTION

SUBJECT: **Human Subjects Research Policy**	PAGE 1 OF 8 . NUMBER: 06-RES-02
RULE/CODE REFERENCE:	SUPERSEDES: 06-RES-02 dated 10/2707
RELATED ACA STANDARDS: 4-4109; 4-4110; 4-4111; 4-4112; 4-4113; 4-4402	EFFECTIVE DATE: November 17, 2011
	APPROVED: 

I. AUTHORITY

This policy is issued in compliance with Ohio Revised Code 5120.01 which delegates to the Director of the Department of Rehabilitation and Correction the authority to manage and direct the total operations of the Department and to establish such rules and regulations as the Director prescribes.

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 Department of Rehabilitation and Correction.

III. APPLICABILITY

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

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 Department of Rehabilitation and Correction (DRC) 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 - The Human Subjects Research Review Committee is a multi-disciplinary team, appointed by the Director or the Director's designee, created to review research studies conducted by individuals outside the Department (and, in some cases, by individuals or groups within the Department) 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 and transitional 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 encourages and uses research conducted by outside professionals. It is the policy of the Ohio Department of Rehabilitation and Correction 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 research projects that are being performed for non-Departmental purposes (such as doctoral dissertations or master's theses) and are to be conducted by researchers outside of the Department, as well as research projects to be conducted by employees or independent contractors in good standing with the Department, must be reviewed and approved by the Human Subjects Research Review Committee. Research activities undertaken by Departmental employees or contract staff for the purpose of Quality Improvement, program monitoring or management audit do not need Human Subjects Research Review Committee review or approval, unless the research is also being used for a student project (a course paper, master's thesis or doctoral dissertation), journal article, book, or other publication.

2. Any research project conducted using information collected directly from offenders, DRC employees, or obtained from the Department concerning offenders, others under the jurisdiction of the Department, or employees of DRC, must adhere to generally-accepted standards of confidentiality of subjects' identity.

3. An Application for Review of Research Proposal form (DRC1836) shall be submitted to the Chair of the Human Subjects Research Review Committee for all proposed research. Each application shall be accompanied by a completed Research Proposal Approval form (DRC1827). Students requesting permission to conduct research within the Department are required to furnish the signature of their academic advisor.

4. During the pre-review process, the Chair of the Human Subjects Research Review Committee may perform an informal review of the research application for general appropriateness. The Chair may encourage the withdrawal of a clearly inappropriate application or may recommend revisions that shall increase the likelihood that the application will be approved.

5. The Human Subjects Research Review Committee 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 Department as human subjects, the application must demonstrate a clear and reasonable nexus for using an offender population. The use of offenders as a simple population of convenience is not sufficient.

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. Privacy and confidentiality concerns and the means of meeting those concerns are detailed in section VI (B) below.

c. In general, projects that represent a risk to offenders are not allowed. It is generally assumed that the coercive environment of prisons or community supervision limits the ability of offenders to freely offer voluntary, informed consent. However, interviews or psychological tests may be acceptable with a reasonable protocol for informed consent.

d. Research projects which involve the use of offenders or employees of DRC as human subjects, or require information about offenders or employees of DRC, and which are to be conducted by offenders or others under the jurisdiction of the Department, are not permitted.

e. Payment of any kind to incarcerated offenders for their participation in research projects is not permitted. Payments of any kind to relatives and friends of incarcerated offenders in exchange for the offender's participation in research projects are not permitted. Payments to offenders on community supervision may be allowed with the approval of the Human Subjects Research Review Committee.

f. The cost of the project to the Department (in 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. In addition, the potential benefits of the research to the Department or the field of criminal justice shall be factored into the decision to approve or disapprove. The researcher must agree to cooperate with the Department's administrative needs, including modification, if necessary, of the project to meet the needs of the setting (prison, field office Operation Support Center) in which the research will be conducted and to present a copy of the final project report to the Department before any public release.

g. Projects that deal with management concerns and not with offenders may not require the oversight and approval of the Human Subjects Research Review Committee. The Director, the Assistant Director, or a Deputy Director may authorize a management study in that person's area of responsibility, or that person may refer the project to the Committee for consideration if publication of the results in outside sources is to occur or the Committee is directed to do so by those listed above.

h. 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 Department are sometimes received. These requests shall be

considered by the Committee, particularly with respect to voluntary informed consent and payment to subjects. Such studies do not need to meet the "clear and reasonable nexus" standard set forth in section VI (A) (5) (a) above.

i. Requests are occasionally received from professional journalists to interview offenders under the jurisdiction of the Department. These requests generally involve the preparation of an article or series of articles in a newspaper or mass circulation (non-academic) publication. However, some requests from journalists may be deemed to meet the definition of research. Upon receipt of such a request, the Committee shall make a determination of whether the request constitutes "journalism" or "research." Requests constituting "journalism" can be approved by the institution Managing Officer or the Department's public information office. Requests constituting "research" shall be referred to the Human Subjects Research Review Committee.

j. Offender 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.

k. In general, although commonly-accepted human subjects' protections apply to incarcerated offenders, offenders on community supervision, and employees of DRC, the standards applied by the Human Subjects Research Review Committee to research protocols involving incarcerated offenders shall be more stringent than those applied to projects involving offenders on community supervision or DRC employees.

l. Projects conducted by individuals with an academic affiliation (faculty or student) must be submitted to and approved by the appropriate college or university Institutional Review Board (IRB) prior to final approval by the Department of Rehabilitation and Correction Human Subjects Research Review Committee. If the Institutional Review Board needs approval from the Department of Rehabilitation and Correction prior to providing their own approval, the Human Subjects Research Review Committee may provide tentative approval.

m. 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. The Human Subjects Research Review Committee can examine research qualifications with respect to education, experience, credentials, licensure, and resources. If necessary, the Committee may ask for verification of credentials.

6. A researcher may be asked to attend the meeting of the Human Subjects Research Review Committee when his or her project is reviewed if an explanation of a particularly complex or problematic study is required.

7. A project that is not approved may be returned to the researcher with suggestions from the Committee about how the project can be modified in order to secure Committee approval. It is the sole responsibility of the researcher to follow up on Committee suggestions.

8. The Committee may designate the Chair or any other Committee member to act on behalf of the Committee in dealing with the requesting researcher with regard to modifications of the research application or in providing guidance and assistance with the actual implementation of the project. At the discretion of the Committee, the Chair or any other Committee member may be given the authority to grant Committee approval to a research application following satisfactory compliance with any changes, additions, or modifications required by the Committee.

9. Following approval by the Committee, the research application shall be reviewed by the Director/designee for final Operation Support Center approval.

10. The Chair of the Human Subjects Research Review Committee shall send the documents relating to an approved research project to the Managing Officer of the facility (or the Superintendent for the Adult Parole Authority) in which the proposed research will be conducted. The Managing Officer (or the Superintendent for the Adult Parole Authority) will, upon receipt of the Operation Support Center approval documents, make a determination of the feasibility of conducting the approved research in the designated facility or field office, and ensure that the research conforms to the policies of the parent agency. For proposed research that will be conducted in a large number of institutions/APA regions, the documents pertaining to an approved project shall be sent to the Deputy Director(s) of the Office of Prisons/Deputy Director of the Division of Parole and Community Services (rather than the Managing Officers or the Superintendent for the Adult Parole Authority) to determine the feasibility of conducting the approved research in the designated facilities / field offices, and ensure that the research conforms to the policies of the parent agency. It is the responsibility of the researcher to contact the Managing Officer(s) (or Superintendent for the Adult Parole Authority/Regional Administrator (s)) to make the appropriate logistical arrangements to implement the project.

11. Researchers both outside and within the Department who receive Committee approval to conduct a research project in the Department are required to furnish a copy of the project final report to the Department through the Human Subjects Research Review Committee. In addition to this requirement, if a researcher outside or within the Department who has received Committee approval to conduct a research project in the Department intends to make public the results of that research (either by publication or by public presentation), that researcher must send a copy of the proposed article or paper to the Chair of the Committee prior to publication or presentation.

12. When a copy of the final project report is received by the Human Subjects Research Review Committee, the Chair shall make that report available to Committee members and may circulate the report to top level managers of the Department and to those departmental managers who might be directly interested in or affected by the findings. If appropriate, managers will be encouraged to further disseminate the results.

13. The research should be conducted within a reasonable timeframe. A reasonable timeframe is determined on a case-by-case basis, and depends upon the design of the research in question. If there are concerns regarding the length of time a researcher takes to conduct the research, the Committee reserves the right to review the research again to determine if the research should be permitted to continue. Researchers may be asked to resubmit an application for continuing the current research proposal. The application should include a description of the research completed to date, an explanation regarding the need to continue the research, and the estimated completion date of the research.

14. The applicant may request an endorsement letter from DRC to meet requirements from a funding source or University's IRB. The Chair/designee shall review the request and may approve the endorsement letter if the research proposal is beneficial to DRC, if the research proposal is not a burden to DRC, or if it is determined the research proposal is in compliance with guidelines dealing with the use of human subjects in research and with professional research standards. However, the research proposal will undergo a full review and must be approved by the Committee and other interested parties (Director's designee at Operation Support Center, Managing Officer(s), Deputy Director of DPCS, Regional Administrator(s) of APA, etc.) before the applicant is authorized to conduct the research study.

B. Privacy and Confidentiality Concerns

1. All proposals to conduct research involving offenders under the jurisdiction of the Department or which require information about those offenders must address the issues of privacy and confidentiality in the research protocol. The Human Subjects Research Review Committee shall review the protocol to ensure that the project will not directly or inadvertently result in the disclosure of offender related information.

2. If, during the Committee's review, it appears that appropriate steps to ensure privacy and confidentiality of information have not been planned, the Chair of the Committee or a member of the Committee may be designated to clarify the situation with the requesting researcher. If there is a possibility that private offender information might be revealed, the research application must be revised to meet the Department's privacy and confidentiality standards before the project can be approved.

3. Following approval, the Chair of the Committee or any other Committee member may be designated to work with the researcher to review confidentiality practices. A proven violation of the Department's confidentiality standards shall result in a temporary or permanent suspension of the project.

C. Proscription of Medical, Pharmaceutical, and Cosmetic Research

1. The participation of offenders under the jurisdiction of the Department in medical, pharmaceutical, and/or cosmetic projects is prohibited unless there is clear benefit to the individual offender based on his/her need for a specific medical procedure or pharmaceutical that is not generally available. Participation of offenders in medical or pharmaceutical testing purely for experimental or research purposes is not permitted.

2. When the Chair of the Human Subjects Research Review Committee receives a proposal that the Chair believes is a medical or pharmaceutical proposal, the Chair shall contact the researcher and explain this policy. After review of the proposal under the requirements of this policy, the Chair may deny the request. If the proposal is denied by the Chair, the project researcher may request a review by the full Committee.

3. A medical or pharmaceutical project may be considered under one set of circumstances. If there are offenders in the prison system who suffer from medical conditions for which all conventional treatment modalities and alternatives have been exhausted, and for whom the only remaining treatment (or drug) is the one being proposed as a part of the medical or pharmaceutical experiment, and the treatment (or drug) will have an immediate therapeutic benefit to the participant, then the project may be considered. In these circumstances, the Committee and the Department may authorize participation as a treatment opportunity, rather than as participation in an experimental project. In such cases, all such research must be performed in compliance with all state and federal guidelines.

4. If a researcher wishes to pursue a project under section VI (C) (3), the Committee shall schedule the project for review. When considering medical or pharmaceutical research, the Committee shall include, in addition to the regular Chair and members, the Chief of the Bureau of Medical Services or designee, and the Director of the Correctional Institution Inspection Committee (CIIC) of the Ohio Legislature or designee. If it is not feasible for the Director or designee of the CIIC to review the research, then the Director of the DRC shall appoint an offender advocate for this purpose. The Department's Legal Services section shall either designate a representative to the Committee or will review the proposal and provide its recommendation to the Committee in writing.

5. If it is determined by the Committee and the Chief, Bureau of Medical Services, that the research proposal would create genuine treatment alternatives for some offenders who would otherwise have exhausted other reasonable medical and/or pharmaceutical possibilities for their condition, the Committee may consider the proposal on its merits.

6. The review of medical and pharmaceutical proposals shall be especially scrupulous. In addition to standard requirements, the project must have:

   a. Either a university-based Human Subjects Research Review Committee approval or a similar approval from a federal funding agency of the protocol, should the project not be university-based;

   b. A clear and comprehensive 'informed consent' procedure;

   c. An opinion by the Department's Legal Services section that the project is in the best interests of offender participants and that the Department will incur no significant liability from the project; or

   d. Concurrence from the Director of the Correctional Institution Inspection Committee that, in his or her judgment, the decision of the Committee is in the best interests of

the particular class of offenders. If it is not feasible for the Director of the CIIC to perform this function, then an offender advocate shall be appointed by the Director of the DRC.

Related Department Forms:

Research Proposal Approval form	DRC1827
Review of Research Proposal form	DRC1836