



Operating Procedure

Effective Date May 1, 2013	Number 020.1
Amended	Operating Level Department

Supersedes
Operating Procedure 020.1 (4/1/10)

Authority
COV §32.1-162.15 through 162.20, §53.1-5.1

Subject
RESEARCH CONDUCTED IN DOC UNITS

ACA Standards
4-4108 through 4-4113; 4-ACRS-7D-12;
4-APPFS-3D-35, 4-APPFS-3D-36, 4-APPFS-3D-37;
2-CO-1F-09, 2-CO-1F-10, 2-CO-1F-11, 2-CO-1F-12,
2-CO-1F-13, 2-CO-1F-15

Incarcerated Offender Access
Yes No

FOIA Exempt Attachments Yes No #1 No

Office of Primary Responsibility
Research and Management Services

I. PURPOSE

This operating procedure establishes protocols for the conduct of research by individuals or organizations within Department of Corrections units.

II. COMPLIANCE

This operating procedure applies to all units operated by the Department of Corrections (DOC). Practices and procedures shall comply with applicable State and Federal laws and regulations, Board of Corrections policies and regulations, ACA standards, PREA Standards, and DOC directives and operating procedures.

III. DEFINITIONS

Human Research - Any systematic investigation utilizing human subjects which may expose such human subjects to physical or psychological injury as a consequence of participation as subjects and which departs from the application of established and accepted therapeutic methods appropriate to meet the subjects' needs.

Legally Authorized Representative - (i) The parent or parents having custody of a prospective subject, (ii) the legal guardian of a prospective subject, or (iii) any person or judicial body authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research. For the purposes of this definition, any person authorized by law or regulation to consent on behalf of a prospective participant to his participation in the particular human research shall include an attorney-in-fact appointed under a durable power of attorney, to the extent the power grants the authority to make such a decision. The attorney-in-fact shall not be employed by the person, organizational unit, or agency conducting the human research and shall not be authorized to consent to nontherapeutic medical research. No official or employee of the organizational unit or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.

Minimal Risk - The risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Non-therapeutic Research - Human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the human subject.

Participant or Human Participant - A living individual whether personnel or inmate, probationer, or parolee about whom an investigator (whether professional or student) conducting research obtains (i) data through intervention or interaction with the individual, or (ii) identifiable private information. "Intervention" includes both physical procedures by which data are gathered and manipulations of the participant or participant's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and participant.

Private Information - Information about behavior that occurs in a context in which an individual can

reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable in order for obtaining the information to constitute research involving human participants.

Research - The systematic development of knowledge essential to effective planning and rational decision making. It involves the assessment of current knowledge on conceptual problems selected, statement of those problems in researchable format, design of methodologies appropriate to the problems, and the application of appropriate analytical techniques to the data. Research findings should provide valuable information to management for policy options.

Researcher - An individual who has professional standing in the pertinent field or is supervised directly by such an individual.

Research Project - The systematic collection of information, analysis of data, and preparation of a report of findings

Voluntary Informed Consent - The knowing consent of an individual so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. With regard to the conduct of human research, the basic elements of information necessary to such voluntary informed consent shall include:

- A fair explanation to the individual of any procedures to be followed and their purposes, including identification of any procedures which are experimental
- A description of any attendant discomforts and risks reasonably to be expected
- A description of any benefits reasonably to be expected
- A disclosure of any appropriate alternative procedures that might be advantageous for the individual
- An offer to answer any inquiries by the individual concerning the procedure
- An instruction that the individual is free to withdraw his voluntary informed consent and to discontinue participation in the human research at any time without prejudice to him

IV. PROCEDURE

A. Research in the Department of Corrections

1. Because research provides valuable information for correctional professionals in managing programs, operations, and offender populations, the DOC and each operational unit support, encourage, engage in, and use research conducted by DOC staff and outside professionals. (4-4108, 4-4109; 4-APPFS-3D-35; 2-CO-1F-10, 2-CO-1F-11) Proper precautions must be exercised for the protection of the research participant's rights and for the overall safety and security of the public, the researcher, and the DOC unit.
2. For internal agency research conducted for DOC purposes, the Director and Executive Staff, in cooperation with Research and Management Services, participate with researchers in deciding questions to be addressed, data to be gathered, and provide input into how that data should be presented. (4-APPFS-3D-36)
3. No research involving the DOC, other than internal agency research conducted for DOC purposes, shall be initiated without a *Research Proposal* (see the *General Requirements for Human Subjects Research Proposal Submission* Section of this operating procedure) reviewed and approved by the DOC Research and Management Services who will have the following responsibilities: (4-4112; 4-APPFS-3D-37; 2-CO-1F-12)
 - a. Review all research projects for compliance to this and other applicable operating procedures
 - b. Establish research priorities consistent with the needs of the DOC
 - c. Review the design of the research, ensure that the research projects do not violate basic research standards

- d. Regulate the number and timetable of research projects, so as not to disrupt the normal functioning of any DOC operational unit
- e. Research proposals requiring DOC data are referred to the DOC Data Governance Committee to determine if the researcher may be given access to the requested data.
- f. Determine if the research is subject to the human research review requirements of COV §§32.1-162.15 through 162.20
- g. The DOC *Human Subject Research and Review Committee* shall review and approve *Research Proposals* involving human subjects.
- h. After its review, DOC Research and Management Services shall prepare a *Research Brief* summarizing the *Research Proposal* with comments, and if applicable, *Human Subject Research and Review Committee* approval or comments.
 - i. The *Research Brief* with additional materials as needed and requested will be provided to the Director or designee for review and approval.
 - ii. Research projects of limited scope i.e., one institution or Probation and Parole District, may be reviewed and approved at the Regional level with copies of approval memos provided to the Chief of Corrections Operations.
- i. After its review and obtaining necessary approvals, and prior to initiation of a study involving a specific organizational unit, DOC Research and Management Services shall provide an approval memo and necessary information describing the project to the Unit Head and Regional Operations Chief as notification of the approved project.
- j. DOC Research and Management Services shall keep the *Research Proposal* on file.

B. Research Agreement

1. The principal researcher must submit a signed, written [Research Agreement](#) 020_F2 with the *Research Proposal* indicating that the principal researcher and/or staff under their supervision have read, understand, and agree to abide by DOC research procedures.
2. The *Research Agreement* shall establish a time line for the research project and the specific date when the researcher shall submit the final report to DOC Research and Management Services. In the case of student research, the student's academic advisor must sign the *Research Agreement* indicating endorsement of the research project.
3. DOC participation in the proposed research project shall occur only when the procedural and applicable human research reviews are completed and the Director, Chief of Corrections Operations, or applicable Deputy Director signs an approval memo on behalf of the DOC.

C. General Requirements for Human Subjects Research Proposal Submission

1. See the following website: <http://www.vadoc.virginia.gov/resources/research/default.shtm> for current information and contacts for research to be conducted in the Department of Corrections
2. Submit via e-mail, if possible, the *Research Proposal* (see Attachment 1 for suggested outline) and [Research Agreement](#) 020_F2. Please limit the proposal to approximately 20 pages, not including curriculum vitae, surveys, references, tables, and other related matter.
3. The *Research Proposal* must include a thorough description of the study including:
 - a. Timeline
 - b. Research Design
 - c. Sampling Methods
 - d. Methods of Analysis
 - e. Potential costs to the Department of Corrections (DOC) (including required resources from the DOC such as personnel, supplies/materials, equipment, workspace, access to participants and files, etc.)
 - f. A discussion of the proposal in the context of relevant literature

- g. Any surveys or instruments to be used
 - h. Informed consent form(s)
 - i. The university's IRB approval (if applicable)
 - j. Curriculum vitae of all persons named as investigators and/or project advisors.
4. Please discuss the benefits to the DOC as well as the field of study.
 5. Research conducted at the Virginia Department of Corrections must conform to current [Regulations for Human Subject Research](#).
 6. No human research may be conducted without informing the participant or their legally authorized representative in writing of the risks, procedures, and discomforts of the research.
 7. The voluntary informed consent of the participant or their legally authorized representative to participate in the research must be documented in writing.
 - a. If the study participant is under DOC supervision, the informed consent must be supported by signature of a witness.
 - b. For a study involving incarcerated participants, consent should clearly state that offenders may contact the researcher in writing with questions about the study. The informed consent form should include a contact address but not a phone number. Upon release, the offender may contact the researcher by phone if any questions arise.
 - c. The researchers shall maintain completed consent forms in a secured place for at least 3 years.
 8. Once complete materials are submitted, the proposal will go before the Human Subject Research Review Committee. If approved (after any revisions), the DOC Director or designee must approve the study. This process takes at least two months.

D. Research Standards

1. Credentials - The principal researcher shall have academic or professional standing in the pertinent field or job-related experience in the areas of study or be directly supervised by such a person.
2. Ethics - The research shall conform to the appropriate standards of ethics of professional societies such as the American Psychological Association, the American Sociological Association, and the National Association of Social Workers, or other equivalent.
3. Protection of Rights - The principal researcher is responsible for the conduct of his staff and assumes responsibility for the protection of the rights of individuals involved in the project.
4. Confidentiality/Anonymity
 - a. The privacy of participants will be maintained during all research. (2-CO-1F-15)
 - b. Project information given by individuals to the researcher shall be kept confidential or anonymous depending on the study design.
 - c. This does not preclude the reporting of results in aggregated form that protects the identity of individuals, or the giving of raw data to Research and Management Services for possible further analysis.
 - d. The confidentiality of any such raw data shall be monitored by Research and Management Services.
 - e. Persons who breach confidentiality/anonymity shall be subject to sanctions in accordance with applicable laws, policies, and procedures.
5. Participant Incentives: The opportunity to participate in research is considered sufficient incentive for participation, and the offering of additional incentives is prohibited without specific approval from the Director or designee. Sentence reduction and/or pecuniary compensation are prohibited as incentives.

E. Department of Corrections units may cooperate, insofar as resources permit, with *Research Proposals*,

which meet the following conditions: (4-ACRS-7D-12)

1. The research shall comply with the Board of Corrections *Regulations for Human Subject Research*, all other applicable laws, rules, and regulations, and will be in compliance with professional and scientific ethics and with state and federal guidelines for the use and dissemination of research findings. (4-4111)
 2. The research shall not interfere with the rights of offenders or DOC staff.
 3. Research involving known and substantive physical, mental, or emotional risk to the participants, including the withholding of any prescribed program or treatment is specifically prohibited.
 4. The research findings shall not identify individual participants. The confidentiality/anonymity of all offenders and other parties engaged in the research will be maintained.
 5. The confidentiality of all records and information shall be protected in accordance with applicable laws, rules, and regulations.
 6. The proposed research shall not interfere significantly with ongoing programs or operations of the DOC operational unit.
 7. The proposed benefits of the research should justify DOC involvement in the project.
 8. DOC operational unit personnel will support and assist as needed in research projects and evaluations conducted either within the DOC or in collaboration with approved external researchers. (4-4110)
 9. Medical research shall only be conducted in accordance with Operating Procedure 701.1, *Health Services Administration*.
- F. Consent of Participant - The following stipulations govern voluntary offender participation in non-medical, non-pharmacological, and non-cosmetic research programs. (4-4113, 2-CO-1F-13)
1. No offender shall be subjected to experimentation or participation in research projects against their will.
 - a. Written consent shall be required of each participant in research projects documented via a [Voluntary Consent to Participate in Research](#) 020_F3 or an equivalent consent document prepared by the researcher and approved by DOC Research and Management Services.
 - b. This consent statement shall identify any possible risks
 - c. The *Consent* shall stipulate that the offender may withdraw from participation at any time without penalty.
 - d. This shall not preclude the use of offender case records without the consent of the offender where interview or questionnaire methods are not used.
 2. Informed Consent: Informed consent shall not include any language through which the human subject waives or appears to waive any of his legal rights, including any release of any individual, facility, or agency or any agents thereof from liability or negligence. The human subject shall sign all informed consent forms confirmed by an acceptable witness.
 - a. Minor/Incompetent Consent: If the human subject is not competent at the time consent is required, informed consent shall be subscribed to in writing by the subject's legally authorized representative. Notwithstanding consent by a legally authorized representative, no competent person who is otherwise capable of rendering informed consent shall be forced to participate in any human research.
 - b. Non-therapeutic Consent: No legally authorized representative may consent to non-therapeutic research unless it is determined by the *Human Subject Research and Review Committee* that such research will not involve greater than minimal risk to the human subject.
 3. Waiver of *Consent to Participate in Research*: The requirement for documented informed consent may be waived by the DOC if there is no risk at all. In certain situations where the only record

linking the subject and research would be the consent document and the only significant risk would be that resulting from a breach of confidentiality, informed consent is not required. Final determination of waivers shall be the responsibility of the *Human Subject Research and Review Committee*.

G. Research Findings (2-CO-1F-09)

1. Progress Reports: At the time the *Research Agreement* is signed, dates for progress reports may be established. These reports will inform DOC Research and Management Services of research progress and any difficulties encountered which might delay or preclude completion of the research project.
2. Final Report: An electronic copy of the final report must be submitted to DOC Research and Management Services.
3. DOC Research and Management Services has the right to reproduce the report for official DOC use only.
4. The principal researcher shall maintain records adequate to enable the appropriate DOC administrative staff (Unit head or above) to ascertain the status of the research project at any given time.

H. Publication Rights

1. Research proposals are approved with the assumption that they will ultimately be published. Researchers are not permitted to conduct research or publish beyond the approved *Research Proposal* without further review and approval from the *Human Subject Research and Review Committee*.
2. The researcher shall furnish DOC Research and Management Services with an electronic copy of the publication.
3. The Department of Corrections shall be permitted to use the data collected in the research project and to reproduce the materials as they are published.
4. Without the explicit written approval of the researcher, the DOC should not publicly distribute any dissertation or thesis material which the researcher has not published or presented publicly or professionally.
5. Without prior approval from the *Human Subject Research and Review Committee*, research conducted by employees or agents (including but not limited to interns, volunteers, contractors, and vendors) of the DOC is the property of the Department of Corrections and cannot be published without the approval of the Director or the appropriate Chief of Corrections Operations or Deputy Director.

V. REFERENCES

Operating Procedure 701.1, *Health Services Administration Regulations for Human Subject Research*, 6VAC15-26

VI. FORM CITATIONS

[Research Agreement](#) 020_F2

[Voluntary Consent to Participate in Research](#) 020_F3

VII. REVIEW DATE

The office of primary responsibility shall review this operating procedure annually and re-write it no later than May 1, 2016.

Signature Copy on File

3/25/13

N. H. Scott, Deputy Director of Administration

Date