



# Virginia Department of Corrections

## Community, Media, and Other Agency Relations

### Operating Procedure 020.1

#### *Research Conducted in DOC Units*

#### **Authority:**

Directive 020, *Cooperation with Other Agencies*

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## REVIEW

The Content Owner will review this operating procedure annually and re-write it no later than three years after the effective date.

## COMPLIANCE

This operating procedure applies to all units operated by the Virginia Department of Corrections (DOC). Practices and procedures must comply with applicable State and Federal laws and regulations, American Correctional Association (ACA) standards, Prison Rape Elimination Act (PREA) standards, and DOC directives and operating procedures.

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## DEFINITIONS

**Human Research** - Any systematic investigation, including research development, testing and evaluation, utilizing human subjects, that is designed to develop or contribute to generalized knowledge.

**Legally Authorized Representative** - In the following specified order of priority, (i) the parent or parents having custody of a prospective subject who is a minor, (ii) the agent appointed under an advance directive, as defined in COV §54.1-2982, executed by the prospective subject, provided the advance directive authorizes the agent to make decisions regarding the prospective subject's participation in human research, (iii) the legal guardian of a prospective subject, (iv) the spouse of the prospective subject, except where a suit for divorce has been filed and the divorce decree is not yet final, (v) an adult child of the prospective subject, (vi) a parent of the prospective subject when the subject is an adult, (vii) an adult brother or sister of the prospective subject or (viii) 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 such subject's participation in the particular human research will 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 must not be employed by the person, organizational unit, or agency conducting the human research and will not be authorized to consent to non-therapeutic medical research. No official or employee of the organizational unit or agency conducting or authorizing the research will 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 staff, 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.

**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.

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

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

**Voluntary Informed Consent** - The knowing and voluntary agreement, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion, of a person who is capable of exercising free power of choice. For the purposes of human research, the basic elements of information necessary to such consent will include:

- A reasonable and comprehensible explanation to the person of the proposed procedures or protocols to be followed, their purposes, including descriptions of any attendant discomforts, and risks and benefits reasonably to be expected;
- A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the person;
- An instruction that the person may withdraw their consent and discontinue participation in the human research at any time without prejudice to them;
- An explanation of any costs or compensation which may accrue to the person and, if applicable, the availability

of third-party reimbursement for the proposed procedures or protocols; and

- An offer to answer and answers to any inquiries by the person concerning the procedures and protocols.

## PURPOSE

This operating procedure establishes protocols for the conduct of research by individuals or organizations with Department of Corrections (DOC) staff, state responsible inmates in DOC facilities or local jails, and probationers/parolees on community supervision with the DOC.

## PROCEDURE

### I. Research in the Department of Corrections

- A. Because research provides valuable information for correctional professionals in managing programs, operations, and inmate/probationer/parolee populations, the DOC and each operational unit support, encourage, engage in, and use research conducted by DOC staff and outside professionals. (5-ACI-1F-13, 5-ACI-1F-14; 4-ACRS-7D-12; 4-APPFS-3D-16, 4-APPFS-3D-35; 2-CO-1F-10, 2-CO-1F-11; 1-CTA-1D-02) 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.
- B. For internal agency research conducted for DOC purposes, the Director and senior leadership, in cooperation with the research unit, participate with researchers in deciding questions to be addressed, data to be gathered, and provide input into how that data will be presented. (4-APPFS-3D-36)
- C. No research involving the DOC, other than internal agency research conducted for DOC purposes, will 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 Human Subject Research Review Committee who will have the following responsibilities: (5-ACI-1F-17; 4-ACRS-7D-12; 4-APPFS-3D-36, 4-APPFS-3D-37; 2-CO-1F-12)
  - 1. Review all research projects for compliance to this and other applicable operating procedures.
  - 2. Consult with any applicable content experts as needed.
  - 3. Establish research priorities consistent with the needs of the DOC.
  - 4. Review the design of the research and ensure that the research projects do not violate basic research standards.
  - 5. Regulate the number and timetable of research projects, so as not to disrupt the normal functioning of any DOC unit.
  - 6. Determine if the research is subject to the human research review requirements of COV §32.1-162.16, *Definitions* through COV §32.1-162.20, *Applicability of federal policies*.
  - 7. The Human Subject Research Review Committee will review and approve *Research Proposals* involving human subjects.
  - 8. After its review, the chairperson of the Human Subject Research Review Committee will prepare a *Research Brief* summarizing the *Research Proposal* with comments, and if applicable, a letter of approval.
    - a. The *Research Brief* with additional materials as needed and requested will be provided to the Director or designee for review and approval.
    - b. Research projects of limited scope e.g., one facility or P&P District, may be reviewed and approved at the regional level with copies of approval memos provided to the relevant Deputy Director.
  - 9. After review and approval of the *Research Proposal*, and prior to initiation of a study involving a specific unit, the chairperson of the Human Subject Research Review Committee will provide an approval memo and necessary information describing the project to the Unit Head and Regional Administrator as notification of the approved project.
  - 10. The research unit will keep the *Research Proposal* on file in accordance with the Library of Virginia retention guidance.

- D. The chairperson of the Human Subject Research Review Committee will submit to the Governor, the General Assembly, and the Director of the DOC or designee, at least annually, a report on the human research projects reviewed and approved by the Human Subject Research Review Committee, including any significant deviations from the approved research projects. (2-CO-1F-04)

## II. Research Agreement

- A. 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.
- B. The *Research Agreement* will establish a timeline for the research project and the specific date when the researcher will submit the final report to the Human Subject Research Review Committee. In the case of student research, the student's academic advisor must sign the *Research Agreement* indicating endorsement of the research project.
- C. DOC participation in the proposed research project will occur only when the procedural and applicable human research reviews are completed and the Director, Chief Deputy Director, Deputy Directors, or applicable/appropriate designee signs an approval memo on behalf of the DOC.

## III. General Requirements for Human Subjects Research Proposal Submission

- A. Submit via email, the *Research Proposal* 020\_F14 and *Research Agreement* 020\_F2. Limit the proposal to 20 pages, not including curriculum vitae, surveys, Institutional Review Board (IRB) approval letter, references, tables, and other related attachments.
- B. The *Research Proposal* must include a thorough description of the study including:
1. Date the complete proposal package was submitted to the Human Subject Research Review Committee
  2. Title
  3. Purpose
  4. Background and literature review
  5. Hypothesis
  6. Methodology for testing hypothesis (Research design, sampling methods, surveys or instruments, methods of analysis)
  7. Informed consent process (if applicable)
  8. IRB approval letter from the university of primary researcher
  9. References
  10. Time frame
  11. Benefit to the DOC, as well as the field of study
  12. Department resources required (Staff, supplies/materials, equipment, workspace, access to participants, etc.)
  13. Curriculum vitae (Principal Investigators, Project Advisors)
- C. 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.
- D. The voluntary informed consent of the participant or their legally authorized representative to participate in the research must be documented in writing.
1. If the study participant is under DOC supervision, the informed consent must be supported by the signature of a witness.
  2. For a study involving inmate/probationer/parolee participants, consent should clearly state that

inmates/probationers/parolees may contact the researcher in writing with questions about the study. The informed consent form will include a contact address but not a phone number. Upon release, the inmate/probationer/parolee may contact the researcher by phone if any questions arise.

3. The researchers must maintain completed consent forms in a secured place for at least three years.

E. Once complete materials are submitted, the proposal will go before the Human Subject Research Review Committee.

If approved by the Human Subject Research Review Committee (after any revisions), the DOC Director or designee must approve the study.

#### IV. Research Standards

A. Credentials - The principal researcher or their direct supervisor must have academic, professional, or job-related experience in the areas of study.

B. Ethics - The research must conform to the ethical standards of professional organizations such as The American Psychological Association, The American Sociological Association, The National Association of Social Workers, or other equivalent professional organizations.

C. Protection of Rights - The principal researcher is responsible for the conduct of their staff and assumes responsibility for the protection of the rights of individuals involved in the project.

D. Confidentiality/Anonymity

1. The privacy of participants will be maintained during all research. (2-CO-1F-15)

2. Project information given by individuals to the researcher must be kept confidential or anonymous depending on the study design.

3. This does not preclude the reporting of results in aggregated form that protects the identity of individuals, or the giving of raw data to the research unit for possible further analysis.

4. The research unit must monitor the confidentiality of any such raw data. Persons who breach confidentiality/anonymity will be subject to sanctions in accordance with applicable laws, policies, and operating procedures.

E. Participant Incentives

1. 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.

2. Sentence reduction and/or financial compensation are prohibited as incentives.

#### V. Cooperation with Research Proposals

A. DOC units may cooperate, insofar as resources permit, with *Research Proposals* that meet the following conditions:

1. The research will comply with COV §32.1-162.16, *Definitions* through COV §32.1-162.20, *Applicability of federal policies*, all other applicable laws, rules, and regulations, and will be in compliance with5 professional and scientific ethics and with state and federal guidelines for the use and dissemination of research findings. (5-ACI-1F-16; 4-ACRS-7D-12)

2. The research will not interfere with the rights of inmates/probationers/parolees 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 must not identify individual participants. The confidentiality and anonymity of all inmates/probationers/parolees and other parties engaged in the research will be maintained.

5. The confidentiality of all records and information must be protected in accordance with applicable laws, rules, and regulations.



6. The proposed research must not interfere significantly with ongoing programs or operations of the DOC unit.
  7. The proposed benefits of the research should justify DOC involvement in the project.
- B. DOC staff will support and assist as needed in research projects and evaluations conducted either within the DOC or in collaboration with approved external researchers. (5-ACI-1F-15)
- C. Medical research will only be conducted in accordance with Operating Procedure 701.1, *Health Services Administration*.

## VI. Consent of Participant

- A. The following stipulations govern voluntary inmate/probationer/parolee participation in non-medical, non-pharmacological, and non-cosmetic research programs: (5-ACI-1F-18; 4-ACRS-7D-12; 2-CO-1F-13)
1. No inmate/probationer/parolee will be subjected to experimentation or participation in research projects against their will.
  2. Written consent will be required of each participant in research projects documented via a *Voluntary Informed Consent to Participate in Research* 020\_F3 or an equivalent consent document prepared by the researcher and approved by the Human Subject Research Review Committee. This consent statement will identify any possible risks.
    - a. The *Voluntary Informed Consent to Participate in Research* 020\_F3 must stipulate that the inmate/probationer/parolee may withdraw from participation at any time without penalty.
  3. The *Voluntary Informed Consent to Participate in Research* 020\_F3 will not preclude the use of inmate/probationer/parolee case records without the consent of the inmate/probationer/parolee where interview or questionnaire methods are not used.
- B. Informed consent will not include any language through which the human subject waives or appears to waive any of their legal rights, including any release of any individual, facility, or agency or any agents thereof from liability or negligence. The human subject must sign all informed consent forms confirmed by an acceptable witness.
1. Minor/Incompetent Consent - If the human subject is not competent at the time consent is required, the subject's legally authorized representative must subscribe to informed consent in writing. Notwithstanding consent by a legally authorized representative, no competent person who is otherwise capable of rendering informed consent will be forced to participate in any human research.
  2. Non-therapeutic Consent - No legally authorized representative may consent to non-therapeutic research unless it is determined by the Human Subject Research Review Committee that such research will not involve greater than minimal risk to the human subject.
- C. The requirement for documented informed consent may be waived by the DOC if there is no risk at all.
- D. Informed consent is not required if:
1. The only record linking the subject and research would be the consent document; and
  2. The only significant risk would be a breach of confidentiality.
- E. Final determination of waivers will be the responsibility of the Human Subject Research Review Committee.

## VII. Research Findings (2-CO-1F-09)

- A. Progress Reports
1. At the time the *Research Agreement* 020\_F2 is signed, dates for progress reports may be established.
  2. These reports will inform the Research Unit of research progress and any difficulties encountered that



might delay or preclude completion of the research project.

- B. Final Report - An electronic copy of the final report must be submitted to the research unit at HSRRC@vadoc.virginia.gov.
- C. The research unit has the right to reproduce the report for official DOC use only.
- D. The principal researcher will 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.

#### VIII. Publication Rights

- A. 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 Review Committee.
- B. The researcher will furnish the Human Subject Research Review Committee with an electronic copy of the publication to HSRRC@vadoc.virginia.gov.
- C. The DOC will be permitted to use the data collected in the research project and to reproduce the materials as they are published.
- D. Without the explicit written approval of the researcher, the DOC will not publicly distribute any dissertation or thesis material that the researcher has not published or presented publicly or professionally.
- E. Without prior approval from the Human Subject Research Review Committee, research conducted by staff or agents (including but not limited to interns, volunteers, contractors, and vendors) of the DOC is the property of the DOC and cannot be published without the approval of the Director, Chief Deputy Director or the appropriate Deputy Director.

#### REFERENCES

COV §32.1-162.16, *Definitions*.

COV §32.1-162.20, *Applicability of federal policies*.

Operating Procedure 701.1, *Health Services Administration*

#### ATTACHMENTS

None

#### FORM CITATIONS

*Research Agreement* 020\_F2

*Voluntary Informed Consent to Participate in Research* 020\_F3

*Research Proposal* 020\_F14