Policy Number:	**102.100**
Title:	**Research**
Effective Date:	**7/17/18**

PURPOSE: To outline the department's procedures and prioritization process for the completion of internal and external research and evaluation.

APPLICABILITY: Department-wide, external researchers requesting access to DOC data and/or to offenders

DEFINITIONS:

Department administration – consists of the commissioner of corrections, deputy commissioners, assistant commissioners, and the commissioner's direct reports.

Human subject research – research or other investigation involving human participants, both adult and juvenile, through intervention or interaction with the individual or from individually identifiable information and includes:

A. The collection of data through:
   1. Examination of individual human beings and their bodily products;
   2. Observation of performance and activities by individual human beings or groups of human beings;
   3. Observation of physical or psychological reactions of individual human beings or groups of human beings to stimuli;
   4. Observation or evaluation of the products of individual performance of tasks or individual reactions to stimuli; and
   5. Examination and analysis of data derived from the types of examinations listed above.
   6. Conducting surveys, interviews or focus groups.

B. The scope of research and/or investigation involving human participants may include physical, chemical, or psychological stimulation of responses, as well as interviews, surveys, observation of behavior, administration of tests, or other techniques of measurement for the evaluation of individual humans.

Human subject research/project application – DOC packet that includes all of the following: research or project methodology, proposed time lines, assignments, and expected outcomes; see Procedure D, "human subject research," below.

Human subjects review board (HSRB) – DOC committee that reviews, approves, and monitors human subject research according to criteria specified in Procedure D, "human subject research,"

below The HSRB is chaired by the research director and includes internal and external members with research experience and expertise.

Informed consent (human subject research only) – a signed statement by a human subject research or project participant indicating that the participant fully understands the protocol, the expectations for participation, the risks/benefits associated with that participation, and the option to discontinue participation at any time. Juvenile participation in a research or project protocol requires the informed consent of the juvenile's parent(s) or legal guardian(s).

Minimal risk (human subject research only) – the probability and degree of harm/discomfort anticipated during the course of the human subject research is no greater than the harm/discomfort encountered in the course of one's daily routine or during the performance of routine physical or psychological examinations.

Planning and performance unit – the unit that receives and initially reviews all department research and evaluation project proposals. The planning and performance unit fulfills data requests, completes legislative reports, and conducts policy and administrative operations research.

Policy and administrative operations research – consists of data collection and analysis designed to provide basic descriptive information regarding department programs, activities and offender population or other data analysis to answer a specific question. Policy and administrative research does not include human subject research as defined in this policy.

Research and evaluation advisory committee (REAC) – a department advisory group comprised of appointed department employees who review all proposals for policy and administrative operations research by the department. The REAC reviews the merits of research proposals and considers whether sufficient resources exist to complete requested research. If, in the opinion of the REAC, sufficient resources are not available to fulfill a research request, the REAC includes this as a part of any recommendation forwarded to department administration for final action.

Research and evaluation (R&E) master list – a prioritized list of all approved human subjects, policy and administrative research projects that will be conducted by the department (planning and performance, field services, health services, etc.) or external researchers. The master list is maintained on the department intranet.

PROCEDURES:

A. Research initiation

All non-human subject research proposals are submitted to the planning and performance unit on the DOC Research and Evaluation Project Proposal form (attached) and must include:

1. Project name, sponsor's name and contact information.

2. Submittal data and deadline date. If the research is legally mandated, the proposal must indicate "yes" and state the authority mandating the research.

3. Work unit/location of internal requesting party, or agency information of outside requestor.
4. A summary of the research, method, and statement of how the proposed project meets department goals from the DOC strategic plan.

5. Indication of resources that will be dedicated by the requestor, and those needed specifically from the planning and performance unit.

6. Student research projects are not accepted for review.

B. Determination of research type

1. Upon receipt of a completed DOC Research and Evaluation Project Proposal form, the research director or designee determines whether the proposal constitutes a simple request for data or merits a human subject research review. Simple data requests must be fulfilled in accordance with the Minnesota Government Data Practices Act (Minn. Stat. Ch. 13). (See also DOC Policy 106.210, "Providing Access to and Protecting Government Data.")

2. If the research director or designee determines that the proposal involves human subject research, the director returns the proposal to the originator with instructions to complete a Human Subject Research Application Packet (attached) and resubmit (refer to Procedure D "human subject research"). If the research proposal seeks policy and administrative operations research, refer to Procedure C "policy and administrative operations research."

C. Policy and administrative operations research

1. The planning and performance unit makes recommendations to department administration using these processes regarding evaluating specific DOC programs. Research and evaluation advisory committee (REAC) meeting minutes documenting recommendations made are saved on the REAC iShare site.

2. The planning and performance unit adds policy and administrative operations research proposals to the REAC quarterly meeting agenda.

3. At regularly scheduled meetings, the REAC reviews the merits of the proposal and determines whether there are sufficient resources to fulfill the request. If the REAC needs more information, it authorizes contact with the research proponent.
   a) Upon a determination that sufficient resources exist, the REAC adds the request to the research and evaluation (R&E) master list and forwards it to the planning and performance unit for action.

   b) If the REAC determines that insufficient resources exist to complete the research, it refers the research proposal to the commissioner for consideration at the next scheduled department heads' meeting to take final action on the research proposal and that group may approve, disapprove, or modify the REAC recommendation.

c) Rejected proposals are returned to the research proponent. If the research is approved, REAC places it on the R&E master list.

4. The assigned unit completes the research identified on the R&E master list. Operational personnel may assist research personnel in carrying out research and evaluation.

5. The planning and performance unit maintains records of all policy and administrative operations research proposals, changes to protocols, and official department correspondence regarding research projects, for a minimum of five years after project completion. The records are available to department staff upon request.

6. Department staff must not engage in research that impedes the ability of the staff to do their jobs, interferes with their responsibilities, or takes advantage of state time, facilities, supplies, or influence for private gain (see Policy 103.220, "Personal Code of Conduct of Employees").

7. Any research conducted by department staff on department time or using department resources is the intellectual property of the department.

D. Human subject research

1. Upon determining that the proposal involves human subject research and was not a student proposal, the research director or designee returns the proposal to the originator for completion of a Human Subject Research Application Packet (attached).

2. The principal researcher must submit the Human Subject Research Application Packet to the research director.

3. The research director, along with designated staff researchers, reviews all incoming research proposals and makes recommendations regarding feasibility, utility, and acceptability of the proposal according to established criteria and forwards those deemed appropriate for review to the human subjects review board (HSRB).

4. The HSRB reviews all forwarded human subject research proposals and makes a written recommendation for approval, disapproval, or further HSRB review.
   a) The HSRB pays special attention to the amount of direct offender contact required for the research.
      (1) The research director contacts the warden of the affected facility and requests that a facility contact be assigned to determine impact on the facility, as well as to serve as facility liaison for approved research projects.

(2) For direct contact that is proposed to exceed ten hours per week, the researcher(s) must submit to tuberculosis (TB) screening (refer to Policy 105.180, "Tuberculosis Control for Applicants, Employees, Contractors, Volunteers, and Students").

(3) After screening, the HSRB votes to recommend approving, conditionally approving, tabling, suspending, or denying the research proposal.

(4) The research director forwards the researcher a written notice of any suspended, tabled, or denied results.

(5) Requests that receive a recommendation for approval are forwarded to REAC for review at the next scheduled quarterly REAC meeting.

b) The HSRB must not review any research proposal more than twice, which includes proposals that have been revised and resubmitted.

c) In making its determination, the HSRB convenes as needed to conduct the final review of any research proposal that is deemed psychological or medical in nature, that has not obtained HSRB/human subjects approval, or that demonstrates more than minimal risk to subjects.

d) The REAC reviews any human subject proposals received from the HSRB and votes to recommend to approve, conditionally approve, or deny. Any proposals recommended for approval are forwarded to the commissioner for consideration and final decision at the next scheduled department heads' meeting.

e) The research director provides written results from the department heads' meeting review to the requestor.

5. Requirements for human subject research proposals:

a) The names and contact information for all researchers who will be involved in the project;

b) Documentation of prior endorsement/approval by a recognized research organization (e.g., a university, college, or private foundation) certifying that the research proposal meets established professional standards. Undergraduate researchers may substitute documentation of faculty sponsorship for approval consideration;

c) A written statement of approval from a recognized research organization's human subjects committee;

d) An abstract summarizing the objectives, methods, and implications of the research;

e) A literature review explaining the foundation and relevance of the research;

f) A concise research question, including the hypotheses to be tested;

g) A list of facility resources (including staff time) to be used for the study. If the researcher is a department staff member and the research is not considered a part of his/her regular job responsibilities, this portion of the research proposal must also contain a discussion of how the researcher will maintain the separation of work and research duties, including a paragraph noting when the research will be conducted and what resources used;

h) A description of the study population, the process of selecting subjects and/or records, inclusion/exclusion criteria, and the sampling methods to be used;

i) A description of the tasks each subject will be asked to complete (including copies of instruments used for these purposes);

j) A description of the methods used to obtain informed consent;

k) A description of the procedures used to maintain confidentiality;

l) A description of the anticipated risks and benefits of the study;

m) A description of the procedures used to minimize risk and the provisions made to care for subjects in case of accident or injury;

n) A description of how results will be interpreted and communicated, including a provision for the warden's review and comments prior to any publication. Any such comments must be included with the publication of the findings;

o) Follow-up provisions, when appropriate, taking into account the varying lengths of individual offender's sentences;

p) A description of how results will be interpreted and communicated; and

q) A signed Non-Disclosure Agreement (attached).

6. Restrictions on human subject research:

a) Offenders are prohibited from participating in medical, cosmetic, or pharmaceutical testing for research purposes, however, this policy does not preclude individual treatment of an offender based on an offender's need for a specific drug or medical procedure that is not readily available.

b) Incarcerated offenders are prohibited from accepting financial remuneration from participation in a research study.

c) Offender participation in medical or pharmaceutical research is limited to therapies likely to benefit the offender as a subject. Such studies must not present more than minimal risk to the offender, must involve full and ongoing offender consent, and must be fully approved by the department HSRB. In addition, such studies must be reviewed and approved by the DOC health services director. This does not apply to routine follow-up by medical staff to study the effectiveness of a prescribed medication.

7. Informed consent requirements for human subject research:

a) Informed consent must be obtained from each participant prior to all human subject research activities. When the participant is an offender, that offender's legal guardian may grant consent, when necessary. Case managers or corrections agents must be informed of an offender's inclusion in any research activities.

b) Informed consent includes:

(1) A brief statement of the research purpose;

(2) An explanation of the research procedures (including how subjects are selected) and an identification of those that are experimental in nature;

(3) A description of the potential discomforts and risks, as well as an explanation of how those discomforts will be addressed;

(4) A description of the potential benefits, to the subject or others;

(5) A disclosure of the appropriate alternative procedures;

(6) An offer to answer any questions and concerns, and the contact information for research personnel assigned to this task;

(7) A written statement (containing no exculpatory language that could be interpreted to mean that the offender waives any legal rights or releases the department/facility of liability for negligence) that the offender/guardian may withdraw consent or discontinue participation at any time without penalty. Procedures for withdrawal must be noted, as must the circumstances under which

researchers may terminate the subject's participation without the subject's consent;

(8) A statement regarding the confidentiality of records/data and how that confidentiality will be maintained; and

(9) A space for signatures and a date.

8. Dissemination limitations on human subject research

a) As a pre-condition to conducting human subject research under this policy, a non-employee must grant in writing to the department a royalty-free and irrevocable right to use the materials/information developed as a result of such research. Use includes reproduction, extraction, and interpretation of research in official department correspondence, reports, Internet sites, and other mediums as department staff determines appropriate.

b) The non-employee must also forward to the research director a hard copy of the data collected during research and a copy of the final report.

E. Any changes to research protocols must be approved in writing by the research director prior to implementation. Projects that fall under the HSRB process must be tracked on the REAC iShare site with the status of each review stage noted with the applicable date.

F. Permission to conduct a research project may be denied or withdrawn at any time for violation of the above procedures or any conditions set by the REAC for policy and administrative research or HSRB for human subject research. A violation of data privacy regulations regarding offender information may subject the researcher to civil or criminal liability.

1. Any report of noncompliance results in the immediate suspension of research and an investigation by the HSRB. Upon completing investigation, the HSRB reports its findings and votes to either dismiss the allegation, reinstate the research with additional protections/supervision, require corrective measures, or terminate the research.

2. If a researcher is found to be in noncompliance after data collection is complete, the board reserves the right to restrict the release of research results.

G. Upon completion, internal and external research reports and results are reviewed by planning, performance, and communications staff prior to dissemination. Final reports are posted on both the department's internal website and the DOC public website.

INTERNAL CONTROLS:

A. REAC meeting minutes document recommendations made and are saved on the REAC iShare site.

B. Projects that fall under the HSRB process are tracked on the REAC iShare site with the status of each review stage noted with applicable date.

C. All policy and administrative operations research proposals, changes to protocols, and official department correspondence regarding research projects are retained by the planning and performance unit according to the retention schedule.

ACA STANDARDS: 2-CO-1F-09 through 2-CO-1F-15; 4-4109 through 4-4113; 1-ABC-1F-05 through 1-ABC-1F-09

REFERENCES: Minn. Stat. §241.01; and Chapter 13
Policy 103.220, "Personal Code of Conduct of Employees"
Policy 105.180, "Tuberculosis Control for Applicants, Employees, Contractors, Volunteers, and Students"
Policy 106.210, "Providing Access to and Protecting Government Data"
Division Directive 500.190, "Health Care Data Practices"
Policy 500.3071, "Behavioral Health Data Practices"
American Psychological Association Ethical Principles of Psychologists and Code of Conduct, Effective 1/1/2003, with amendments effective 1/1/10 and 1/1/2017
Code of Federal Regulations Title 45, Part 46 (45 CFR46)

REPLACES: Policy 102.100, "Research," 2/20/18.
All facility policies, memos, or other communications whether verbal, written, or transmitted by electronic means regarding this topic.

ATTACHMENTS: DOC Research and Evaluation Project Proposal (102.100A)
Human Subject Research Application Packet (102.100B)
Non-Disclosure Agreement (102.100C)
Research Application Packet (102.100D)

APPROVED BY:
Deputy Commissioner, Facility Services
Deputy Commissioner, Community Services
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