

## HEALTH SERVICES POLICY & PROCEDURE MANUAL

North Carolina Department Of Public Safety

SECTION: Administrative – Offender’s Rights

POLICY # AD IV-4

PAGE 1 of 2

SUBJECT: Medical Research

EFFECTIVE DATE: May 2014  
SUPERCEDES DATE: May 2002

---

### PURPOSE

To ensure that any research done on offenders or offender’s medical records in the North Carolina Department of Public Safety (NCDPS), is in compliance with State and Federal guidelines.

### POLICY

Any research done on offenders shall be done in accordance with State and Federal guidelines (Title 45, Part 46 of the code of Federal Regulations, Subpart C) - Protection of Human Subjects/Prisoners) Additional protection pertaining to biomedical and behavioral research involving offenders as subjects establishes the restrictions on the use of offenders as research subjects). This policy applies to research, medical experimentation, psychiatric or psychological experimentation, and social research.

Studies involving offenders may be conducted or supported provided that:

1. They represent minimal or no risk to subject(s)
2. The mandatory requirements are met
3. They cause nothing more than slight inconvenience to subject(s).

Research on practices which have the intent and reasonable probability of improving the health or well-being of the individual offender may be conducted or supported, provided the mandatory requirements are fulfilled.

### PROCEDURE

- A. Prior to granting approval of any research under the provisions of this section, certification must be acquired from the Secretary of Correction/designee that the competency of the investigators and the adequacy of the research facilities involved are sufficient for the conducting a particular research project.
- B. All research conducted within Health Services involving offenders as subjects must be reviewed by the Department of Public Safety (NCDPS) Human Subjects Review Committee through the office of Rehabilitative Programs and Services (formerly Research and Planning.).
- C. Prior to granting approval of any research under the provision of this section, the Director of Rehabilitative Programs and Services/designee must certify that the value of the research to the NCDPS is great enough to outweigh the cost and disruption which the project may cause.

**HEALTH SERVICES POLICY & PROCEDURE MANUAL**

**North Carolina Department Of Public Safety**

**SECTION: Administrative – Offender’s Rights**

**POLICY # AD IV-4**

**PAGE 2 of 2**

**SUBJECT: Medical Research**

**EFFECTIVE DATE: May 2014**  
**SUPERCEDES DATE: May 2002**

---

- D. Prior to granting approval of any research under the provisions of this section, the primary investigator must certify:
1. That all applicable requirements, regulations, and policies concerning the security and privacy of information collected, generated, or used during the project will be strictly observed.
  2. That all information shall be the property of the NCDPS, that no such data shall be used for purposes other than those agreed to in the project without prior written consent from the Director of Rehabilitative Programs and Services/designee, and that all raw data, copies of intermediate conclusions and reports, and final reports will be provided to the NCDPS, except where such provision would be contrary to applicable security and privacy requirements.
  4. That no press conference or other release to the news media concerning the research project, its conduct, or its results, will occur without at least one week’s advance notice to the Director of Rehabilitative Programs and Services/designee of said release and its contents.

*Paula Y. Smith, M.D.*

**3/24/2014**

Paula Y. Smith, MD, Chief of Health Services    Date

SOR: Standards Director