

HEALTH SERVICES POLICY & PROCEDURE MANUAL

North Carolina Department Of Correction
Division Of Prisons

SECTION: Administrative – Patient’s Rights

POLICY # AD IV-4

PAGE 1 of 2

SUBJECT: Medical Research

EFFECTIVE DATE: May 2002

SUPERCEDES DATE: June 1996

PURPOSE

To ensure that any research done on inmates or inmate’s medical records in the Division of Prisons is in compliance with State and Federal guidelines, the Division of Prisons shall fulfill the requirements as set forth by this policy.

POLICY

Any research done on inmates shall be done in accordance with State and Federal guidelines (Federal Register, Volume 43, No. 222, Title 45, Part 46 - Protection of Human Subjects, Sub-part C - Additional protection pertaining to biomedical and behavioral research involving inmates as subjects establishes the restrictions on the use of inmates as research subjects). This policy applies to research, medical experimentation, psychiatric or psychological experimentation, and social research.

Studies involving inmates 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 inmate 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 conduct of that particular research project.
- B. All research conducted within the Division of Prisons involving inmates as subjects must be reviewed by the Department of Correction “Human Subjects Review Committee”.
- C. Prior to granting approval of any research under the provision of this section, the Director of Management Information and Research must certify that the value of the research to the Department of Correction is great enough to outweigh the cost and disruption which the project may cause.
- 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.

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2. That all information shall be the property of the Department of Correction, 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 Management Information and Research, and that all raw data and copies of intermediate conclusions and reports, and final reports will be provided to the Department of Correction, except where such provision would be contrary to applicable security and privacy requirements.
3. 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 Management Information and Research of said release and its contents.



5/14/02

Paula Y. Smith, MD, Director of Health Services

Date

SOR: Standards Director