GEORGIA DEPARTMENT OF CORRECTIONS

Standard Operating Procedures

Policy Name: Medical Research		
Policy Number: 507.04.88	**Effective Date:** 01/27/2022	**Page Number:** 1 of 5
Authority: Commissioner	**Originating Division:** Health Services Division (Physical Health)	**Access Listing:** Level I: All Access

I. Introduction and Summary:

Biomedical or other Research activities using offenders as subjects will be consistent with established ethical, medical, legal, and regulatory standards for human Research. Offenders will be included in Research only on a voluntary basis after giving informed consent. This procedure is applicable to all facilities that house Georgia Department of Corrections (GDC) offenders to include private and county prisons.

II. Authority:

A. Ga. Comp. R. & Regs. 125-4-4-.12;

B. GDC Standard Operating Procedure (SOP): 104.75 Research Guidelines;

C. Code of Federal Regulations: 45 CFR 46;

D. NCCHC 2018 Adult Standard: P-G-06; and

E. ACA Standards: 5-ACI-6C-09, 4-ALDF-4D-18, and 4-ACRS-4C-20.

III. Definitions:

A. **Minimal Risk** - The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives or in the routine medical, dental, or psychological examination of healthy persons.

B. **Research** - A systematic investigation to develop or contribute to generalized knowledge.

C. **Institutional Review Board** - A board comprised of individuals with varying backgrounds, which promotes complete and adequate review of Research activities. The composition and functions of the IRB will comply with Federal Regulations related to Protection of Human Subjects.

IV. Statement of Policy and Applicable Procedures:

A. Types of Research Approved for Offenders:

1. Improvement in the quality of health care and its delivery is dependent upon the advancement of knowledge through research. However, because offenders may be under special constraints that could affect their ability to make a truly voluntary and un-coerced decision to participate as Research subjects, it is important to provide safeguards for the protection of offenders involved in Research activities.

2. Biomedical or behavioral Research involving offenders will be conducted in compliance with Federal Regulations regarding Protection of Human Subjects (45 C.F.R. §46).

3. Research involving offenders may only be conducted to:

   a. Study the possible causes, effects, and processes of incarceration and of criminal behavior provided that the study presents no more than Minimal Risks and no more than inconvenience to the subjects;

   b. Study prisons as institutional structures or offenders as incarcerated persons provided that the study presents no more than Minimal Risks and no more than inconvenience to the subjects;

   c. Provide Research on conditions particularly affecting offenders as a class (e.g., hepatitis vaccine trials) provided that the study may proceed only after approval from the Secretary of the Department of Health and Human Services;

   d. Provide Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases involving the assignment of offenders to control groups that may not benefit from Research, the study may only proceed

after approval from the Secretary of the Department of Health and Human Services.

4. No other types of biomedical or behavioral Research involving offenders will be conducted. This includes aversive conditioning, psychosurgery or the application of cosmetic substances being tested prior to sale to the general public.

B. Special Provisions Protecting Offenders Involved in Research Activities:

1. In addition to regulations generally protecting human subjects involved in biomedical and behavioral Research, The Code of Federal Regulations establishes special provisions that protect offenders involved in Research activities. These special provisions include the following:

   a. An Institutional Review Board (IRB) which is composed of a majority of members who have no association with the correctional facility involved with the Research.

   b. Offender Research participants should not gain any special advantages (e.g., living conditions, medical care, quality of food, amenities, and pay) through participation in Research that may impair their objectivity in deciding upon participation.

   c. The risk of participating in the Research for offenders should be the same as the risk of those who are not incarcerated.

   d. Selection for participation should be fair, impartial and without influence from correctional officers or other offenders. Control groups of offenders should meet the characteristics required for the Research and be randomly selected for participation.

   e. Information regarding participation should be presented in language that the offenders understand.

f. Parole should provide assurance that an offender's participation in Research will in no way affect parole board hearings or decisions.

g. If follow-up examination or care is necessary to the Research, these arrangements should be made even for those who may have served their required sentences or been paroled prior to the conclusion of the Research.

C. Requests to Conduct Medical Research:

1. All requests to conduct medical Research will be sent by the investigator to the GDC Office of Legal Services. The proposal will include the following elements:

   a. The type and purpose of the Research;

   b. Methodology;

   c. Duration of Research;

   d. Involvement of facility staff;

   e. Informed consent document (or rationale for Waiver);

   f. Confidentiality provisions; and

   g. Schedule of periodic status reports to the GDC Health Services Director.

2. The General Counsel shall circulate the Research proposal to the appropriate members of the Executive Team and forwarded their recommendations to the GDC Commissioner for final review.

3. Medical experimental or Research activities involving either offenders or staff will not be undertaken without the prior written approval of the Commissioner for each project.

4. Following the GDC Commissioner's review and approval/disapproval, the Office of Legal Services will notify the investigator of the decision.

D. When offenders who are participants in a community-based Research protocol are admitted to the facility, procedures provide for:

1. Continuation of participation.

2. Consultation with community researchers so that withdrawal from the Research protocol is done without harming the health of the offender.

V. Attachments: None.

VI. Record Retention of Forms Relevant to this Policy: None.