

POLICY OF STATE OF DELAWARE DEPARTMENT OF CORRECTION	POLICY NUMBER G-06	TOTAL PAGES 2
	RELATED NCCHC / ACA STANDARDS: NCCHC: P-G-06 (important), J-G-06 (important), MH-I-05 (important) ACA: 5-6C-4402 (mandatory), 4-ALDF-4D-18 (mandatory), 4-ACRS-4C-20 (mandatory)	
CHAPTER: 11 BUREAU OF CORRECTIONAL HEALTHCARE SERVICES	SUBJECT: MEDICAL AND OTHER RESEARCH	
APPROVED BY THE BUREAU CHIEF: Marc Richman, PhD 01/24/2019 (signature on file with BCHS)		
APPROVED BY THE COMMISSIONER AND EFFECTIVE THIS DATE: Perry Phelps, Commissioner 01/24/2019 (signature on file with BCHS)		
APPROVED FOR PUBLIC RELEASE		

- I. **AUTHORITY:** 11 *Del. C.* §6536 Medical Care

- II. **PURPOSE:** To ensure that offenders are not used for medical, pharmaceutical, or cosmetic experiments and to ensure that any biomedical, behavioral, or other research conducted is consistent with established ethical, medical, legal, and regulatory standards for human research.

- III. **APPLICABILITY:** All Delaware Department of Correction (DDOC) employees and Contract Provider staff, offenders, and any outside healthcare provider servicing DDOC offenders.

- IV. **DEFINITIONS:** See Glossary

- V. **SUMMARY OF CHANGES:** This policy has not changed significantly but the policy number has been updated.

- VI. **POLICY:**
 - A. It is the policy of the DDOC that:
 1. The use of offenders for medical, pharmaceutical, or cosmetic experiments is prohibited.
 2. Offenders are not precluded from participating in clinical trials based on their need for a specific medical intervention if there is some potential benefit to the offender. All federal guidelines and regulations must be followed and the clinical trial protocol must be approved by an institutional review board.
 3. An offender’s individual treatment with an experimental medical procedure or device pursuant to #2 above is undertaken only after the offender has received a full explanation of the positive and negative features of the treatment and the treatment limitations and only with informed consent in accordance with BCHS Policy *G-05 Informed Consent and Right to Refuse*.

4.If biomedical, behavioral, or other research involving offenders is to be conducted, then research will comply with DDOC Policy 6.9 Research Activities. Additionally, research will also comply with all state and federal guidelines such as the Code of Federal Regulations - 45 CFR 46.

- a. There will be guidelines in place that specify:
 - i. The process for obtaining approval to conduct the research
 - ii. The steps to be taken to preserve the subject's rights
- b. When inmates are participants in a community-based research protocol(s) and admitted to a DDOC facility, one of the following must occur:
 - i. There is consultation with the community researcher(s) to ensure that withdrawal from the research protocol is done without harming the health of the offender
 - ii. There is consultation with the community researcher(s) to determine if there is an acceptable way to continue the research protocol (while adhering to security regulations) without harming the health of the offender

5.This does not restrict the collection of aggregate data from health record reviews as long as confidentiality is maintained.

- B. The Contracted Medical Provider shall develop within 30 days of the effective date of this policy, a site-specific procedure for each Level 4 and Level 5 facility implementing this policy and coordinating the procedure with the BCHS.