

POLICY OF STATE OF DELAWARE DEPARTMENT OF CORRECTION	POLICY NUMBER I-06	PAGE NUMBER 1 of 2
	RELATED NCCHC/ACA STANDARDS: P-I-06; J-I-06 (Important)/ 4-4111; 4-4112; 4-4113; 4-4402; 4-ACRS-4C-20; 2-CO-1F-14	
CHAPTER: 11 BUREAU OF CORRECTIONAL HEALTHCARE SERVICES	SUBJECT: MEDICAL AND OTHER RESEARCH	
APPROVED BY THE COMMISSIONER:		
EFFECTIVE DATE: 11/19/07 REVISED: 4/13/2009; 9/15/2015; 08/11/2016		

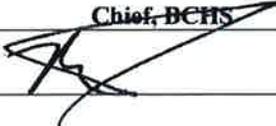
- I. AUTHORITY: Bureau of Correctional Healthcare Services
- II. PURPOSE: The offender has the information to facilitate an informed decision regarding treatment, procedures and examinations.
- III. APPLICABILITY: All Delaware Department of Correction (DDOC) employees and Contract Provider staff, offenders, and any outside healthcare provider servicing DDOC offenders.
- IV. DEFINITIONS: See glossary
- V. SUMMARY OF CHANGES: Changes the approval authority for research and clarifies wording of what is prohibited.
- VI. POLICY:
- A. The use of offenders for medical, pharmaceutical, or cosmetic experiments is prohibited. This does not preclude offender participation in clinical trials that are approved by an institutional review board based on his or her need for a specific medical intervention.
 - B. Offenders may willingly participate in clinical research programs that fulfill all provisions of the federal 45 CFR 46 regulations.
 - C. Access to compassionate use of medications for treatment of medical conditions is made available according to established medical standards and FDA protocols.
 - D. Collection of aggregate medical data and reporting of information is permitted if consistent with the policies and procedures set forth in DOC Policy 6.9 and will be in compliance with all Federal and state guidelines. Such aggregate medical data research proposals shall be submitted to the Planning & Research Unit, which will coordinate review of the request in accordance with DOC Policy 6.9 in partnership with BCHS and the Medical Provider. Offender participation in clinical research

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trials is not subject to review by the Planning & Research Unit; those proposals should be referred directly to BCHS and the Medical Services Contract Provider.

F. The Medical Services Contract Provider shall develop a procedure for referring all aggregate research requests to the Planning & Research Unit and for referring all clinical trial participation requests to BCHS.

Approval:

Marc D. Richman, Ph.D. Chief, BCHS	Date	Robert Coupe Commissioner	Date
	8/2/16		8/11/2016