

POLICY

SUBJECT: Youth Participation in Health-related Research

NUMBER: HC-307-15

APPLICABLE TO: All DJS Employees

APPROVED: _____ /s/ signature on original

Sam Abed, Secretary

DATE: _____ 2/10/16

I. POLICY

The Department of Juvenile Services (DJS) shall ensure all youth participation in biomedical research is consistent with established ethical, medical, legal, and regulatory standards for human research.

II. AUTHORITY

- A. Md. Code Ann., Human Services, §9-203 and §9-204
- B. 45 CFR 46, Basic HHS Policy for Protection of Human Research Subjects
- C. American Correctional Association Standard 4-JCF-4C-48
- D. National Commission on Correctional Health Care (NCCHC) Standards for Health Services in Juvenile Detention and Confinement Facilities, 2011, Y-I-05

III. DIRECTIVES/POLICIES RESCINDED

Youth Participation in Experimental Health Research, 01.12.08

IV. FAILURE TO COMPLY

Failure to comply with the Department's Policy and Procedures shall be grounds for disciplinary action up to and including termination of employment.

V. STANDARD OPERATING PROCEDURES

Standard operating procedures have been developed.

VI. REVISION HISTORY

DESCRIPTION OF REVISION	DATE OF REVISION
Old policy rescinded. New policy issued. Procedures updated to ensure research involving youth are consistent with the existing DJS Research Policy and NCCHC Standards. Policy was reformatted and renumbered.	2/10/16
Procedures revised to prohibit the use of youth in medical, pharmaceutical, or cosmetic experiments and to allow clinical research aimed at improving conditions of confinement.	12/12/17

PROCEDURES

SUBJECT: Youth Participation in Health-related Research

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APPLICABLE TO: All DJS Employees

APPROVED: _____ /s/ signature on original
Linda McWilliams, Deputy Secretary

REVISION DATE: _____ 12/12/17

I. PURPOSE

To provide a systematic and coordinated process to review, approve and document DJS youth participation in health-related research, and to ensure that research in DJS facilities occurs only after obtaining proper consent of youth, and/or legal guardian, as required by law, and approval by DJS and the requesting research investigator's facility's Institutional Review Board (IRB).

II. DEFINITIONS

Informed consent is the written agreement by a patient or guardian to a treatment, examination, or procedure after the patient or guardian receives the material facts about the nature, consequences, and risks of the proposed treatment, examination, or procedure; the alternatives to it; and the prognosis if the proposed intervention is or is not undertaken.

Qualified Health Care Professional includes licensed physicians, physician's assistants, dentists, nurses, nurse practitioners, mental health professionals and others who by virtue of their education, credentials, and experience are permitted by law to evaluate and care for youth.

III. PROCEDURES

- A. All youth participation in research shall be reviewed and approved in accordance with the *DJS Review and Approval of Research Proposals Policy*.
- B. Any research conducted on youth shall meet the standards for research design and control.
- C. As required by law, the investigating research facility's IRB, the DJS Research Committee, the youth and/or their legal guardian must give informed consent in order to participate in any research conducted on the youth while in DJS facilities.

1. Signatory shall be determined based on who (youth or parent) is legally allowed to consent.
 2. Invasive procedures or treatment where there is a risk or benefit to the youth require informed consent documented on a written form containing the signatures of the youth or legal guardian as required by law, and health staff witness.
 3. Any refusal shall be documented and must include the following:
 - a. A description of the nature of the service being refused; and
 - b. Evidence that the youth has been made aware of any adverse consequence to their health that may occur because of the refusal.
- D. If a DJS youth is a participant in a community or hospital-based research study or clinical trial prior to admission to a DJS facility, then DJS staff will consult with the research or clinical investigators to continue, modify, hold, or terminate participation in the research study or trial depending on the safety and feasibility of continuing the research or clinical protocol while in a DJS facility. If a youth's health could be negatively affected by termination or modification to his or her participation in a research study or clinical trial, then DJS shall work with the research or clinical investigators whenever possible to continue participation or otherwise safely modify or withdraw participation in the research study or clinical trial.
- E. DJS qualified health care professionals shall not prescribe, dispense, or administer experimental medication, substances, or other experimental treatment modalities to DJS youth unless as part of an approved research study or clinical trial after obtaining informed consent by the youth and/or legal guardian as required by law, Institutional Review Boards, and the DJS Research Committee. DJS qualified health care professionals shall operate within the bounds of their license(s) and shall follow health practices that are accepted by the medical/health community.
- F. DJS youth shall not be used for medical, pharmaceutical, or cosmetic experiments. This does not preclude individual treatment of a youth based on his or her need for a specific medical procedure that is not generally available.
- G. Clinical research aimed at improving the care or condition of confinement is not prohibited. Institutions electing to perform research shall be in compliance with all state and federal guidelines.
- H. Youth in DJS facilities shall not be forced or coerced to participate in research studies and shall not be subject to negative consequences if they decline to participate in health-related research.

VII. RESPONSIBILITY

The Medical Director is responsible for implementation and compliance with this procedure.

VIII. INTERPRETATION

The Deputy Secretary of Operations shall be responsible for interpreting and granting any exceptions to these procedures.

IX. LOCAL OPERATING PROCEDURES REQUIRED

No

X. DIRECTIVES/POLICIES REFERENCED

DJS Review and Approval of Research Proposals Policy

XI. APPENDICES

None



DJS POLICY AND STANDARD OPERATING PROCEDURES

Statement of Receipt and Acknowledgment of Review and Understanding

SUBJECT: Youth Participation in Health-related Research
NUMBER: HC-307-15
APPLICABLE TO: All DJS Employees
REVISION DATE: December 12, 2017

I have received and reviewed a copy (electronic or paper) of the above titled policy and procedures. I understand the contents of the policy and procedures.

I understand that failure to sign this acknowledgment form within five working days of receipt of the policy shall be grounds for disciplinary action up to and including termination of employment.

I understand that I will be held accountable for implementing this policy even if I fail to sign this acknowledgment form.

SIGNATURE

PRINT FULL NAME

DATE

WORK LOCATION

***SEND THE ORIGINAL, SIGNED COPY TO VERNELL JAMES IN THE DJS OFFICE OF
HUMAN RESOURCES FOR PLACMENT IN YOUR PERSONNEL FILE.***