

YOUTH SERVICES POLICY

Title: Research Next Annual Review Date: 07/01/2018	Type: C. Field Operations Sub Type: 1. General Number: C.1.5
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References: La. R.S.15:574.12(D)(2); "Protection of Human Subjects" 45CFR46; "The Privacy Rule" under the Health Insurance Portability and Accountability Act" (HIPPA) of 1996, 45CFR160 and 45CFR146 (A) & (E); ACA Standards 2-CO-1F-09 through 2-CO-1F-15 (Administration of Correctional Agencies), 2-7080, 2-7081, 2-7082, 2-7083, 2-7084, 2-7085, 2-7087, 2-7088 (Juvenile Probation and Aftercare Services); 4-JCF-6F-06 (Performance-Based Standards for Juvenile Correctional Facilities); YS Policy B.6.1 "Healthcare"	
STATUS: Approved	
Approved By: <i>Mary L. Livers, Deputy Secretary</i>	Date of Approval: 07/01/2013

I. AUTHORITY:

Deputy Secretary of Youth Services (YS) as contained in La. R.S. 36:405. Deviation from this policy must be approved by the Deputy Secretary.

II. PURPOSE:

To establish policy supporting research activities in furtherance of YS overall goals, objectives, and mission while protecting individuals and their rights to privacy and confidentiality; to provide written policy and procedures for processing and reviewing research proposals; to ensure that research is conducted in compliance with applicable federal and state laws and regulations, YS policies, and accepted professional and scientific ethics; and to govern the use and dissemination of research findings.

III. APPLICABILITY:

Deputy Secretary, Assistant Secretary, Undersecretary, Chief of Operations, Deputy Assistant Secretary, Regional Directors, Facility Directors, and any person or entity seeking to conduct research or an evaluation study of a YS secure facility or its youth.

IV. DEFINITIONS:

Human Subject - A living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.

Institutional Review Board (IRB) - A board established in accord with and for the purposes of protecting human research subjects pursuant to 45CFR46.

Minimal Risk - The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

V. POLICY:

It is the Deputy Secretary's policy to encourage and support quality research that furthers the purposes and the mission of YS, while complying with federal and state law as well as accepted professional and scientific ethics, and providing protection for human subjects. It is essential to safeguard the rights of privacy, confidentiality, informed consent, and other pertinent interests of youth, their families, staff, and others during research.

Research requests shall be reviewed in accordance with the procedures outlined herein. Medical, pharmaceutical or cosmetic experiments, or testing for research purposes involving youth, are prohibited. The Deputy Secretary shall review and provide final approval or disapproval for all research requests.

VI. PROCEDURES:

- A. Research request concerning youth assigned to secure care or Community Based Services (CBS) shall be submitted to the appropriate Regional Director for approval. The research request shall be routed from the Regional Director to the Assistant Secretary for initial review. Final authorization shall be provided by the Deputy Secretary.
- B. The person or entity requesting the research project shall provide the following written documentation prior to approval of the request:
 - 1. A formal research proposal, including the names and vitae of the researchers, abstract, purpose, methodology, duration, number of subjects, amount of time required for each subject, dissemination plan, testing or measuring instrument, and any YS resources to be utilized.
 - 2. Documentation of sources of funding, grants awarded, descriptions detailing intentions to respond to official requests for proposals.
 - 3. Institutional Review Board (IRB) application and approval, if applicable.
 - 4. A signed Research Agreement which shall contain a statement that all rights of privacy, informed consent, confidentiality, and protection from harm are met in accordance with professional and scientific ethics, and that the requirements of all applicable federal and state laws, and regulations have been and will continue to be met; and
 - 5. Any other information deemed necessary to the authorization process.

- C. The following factors shall be considered, at a minimum, before staff approve and forward a research request to the Deputy Secretary that:
1. The possible benefits that YS will derive from the research, such as program monitoring and development, and the establishment of goals and objectives that further the YS mission;
 2. The research activities comply with professional and scientific ethics and applicable state and federal laws;
 3. The research presents no more than minimal risk to the youth;
 4. Youth are not denied basic services available to other youth as a result of the research.
 5. The research consists of no more than interviews and/or written questionnaires and surveys, analysis of census and demographic data, or procedures which do not manipulate bodily conditions;
 6. The persons conducting the research shall be qualified to do so;
 7. Facility staff may assist research personnel in carrying out research activities and evaluation;
 8. Any direct youth participation or involvement is voluntary and written consent shall be obtained from youth who are 18 years of age or older; the youth's parents or legal guardians must also consent in writing if the youth is 17 years of age or younger. Informed consent forms must be written at a fourth grade level.
 9. The research activities shall not interfere with the normal operations of the facility, or significantly disrupt the orderly functioning of any office;
 10. All research results are provided to YS in a written report and must be approved by the Deputy Secretary prior to publication or presentation or otherwise shared;
 11. The Deputy Secretary approves the distribution list of research findings and reports.
 12. The research shall be at no cost to YS, unless conducted at YS request.
 13. No studies or research shall be conducted for profit of any person or entity.
 14. Medical, pharmaceutical, or cosmetic experiments or testing for research purposes involving youth are prohibited.

15. Adequate protection is provided for the rights of human subjects.
 16. The rights to privacy, confidentiality, informed consent, and other pertinent interests of the youth, their families, staff, and others are adequately safeguarded during all research;
 17. Research involving the collection of or study of existing data, documents, records, pathological specimens, diagnostic specimens, (1) if not publicly available, or (2) if recorded by the researcher in such a manner that the subjects can be identified, directly or through identifiers linked to the subjects, is considered human research and covered by 45CFR46 "Protection of Human Subjects", and the additional protections that 45CFR46 provides for research involving prisoners and children. Some coded health information in which the code has been derived from identifying information linked to or related to an individual is considered individually identifiable under the HIPPA Privacy Rule, even if it is not characterized as individually identifiable information under 45CFR46.
- D. Reviewing staff shall submit the research proposal, documentation of approval by an authorized IRB, and his or her recommendation for approval or disapproval to the Deputy Secretary. (IRB approval is a minimal requirement prior to submission to the Deputy Secretary and does not guarantee approval of a research request.)
 - E. The Deputy Secretary / Deputy Assistant Secretary shall review the research proposal and ensure that it meets YS overall goals, objectives and mission before approving or disapproving a research request.
 - F. Research projects that are approved by the Deputy Secretary shall be carefully and regularly monitored by the Regional Director and Facility Director to ensure compliance with the provisions of this policy.
 - G. Researchers and research staff shall comply with all applicable YS policies and procedures.
 - H. New or significantly modified programs which result from research should be initiated on a trial basis to determine the impact on YS operations and effect on Public Safety.

Previous Regulation/Policy Number: C.1.5

Previous Effective Date: 06/10/2011

Attachments/References: