SPECIAL PROGRAMS FOR YOUTH	Policy Number: 1.1454
Policy Title: Participation in Research Corresponds to: Title 15, Article 8, Section 1454	Written: 3/7/2013

I. POLICY

A. The use of juveniles for medical, pharmaceutical, or cosmetic experiments, undertaken by either Special Programs for Youth (SPY) Health Care staff or outside researchers, shall be prohibited, except in accordance with the terms of this policy.
    1. Individual treatment of a juvenile, based on his/her need for a specific medical procedure that is not generally available, shall not be precluded.
    2. Participation shall not be a condition for obtaining privileges or other rewards in the facility.

B. In addition, the following principles shall be observed with regard to juveniles' participation in research studies or experiments:
    1. Participation by juveniles in research studies or experiments shall only occur in accordance with standards set forth in the federal regulations concerning Protection of Human Subjects (Title 45 Code of Federal Regulations (CFR) Part 46 Protection of Human Subjects). Juveniles' participation in research studies and experiments shall be limited to research with risk levels as described below:
        a. Research not involving greater than minimal risk (46.404)
        b. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects (46.405).
    2. Juveniles shall not be precluded from receiving "experimental" or "investigational" medical treatments or procedures not otherwise generally available that are designed to meet their individual medical needs, even if such treatments or procedures are available only in the context of a research protocol or clinical trial.
    3. The SPY Health Care staff or students/interns supervised by SPY staff may conduct statistical, epidemiological, psychological, social, and management research involving the study of juveniles' health status and related factors.
    4. Other medical, pharmaceutical, or cosmetic experiments undertaken by SPY Health Care staff, students/interns supervised by SPY staff, or by outside researchers shall be prohibited.

II. PROCEDURES

A. Research studies or experiments shall be conducted in accordance with I.A.-D, above and with the approval of the Chief Probation Officer, the Director of SPY, and the Supervising Juvenile Court Judge. The approval process and follow-up procedures shall be outlined below:

    1. SPY staff and/or students/interns supervised by SPY staff [investigators (s)] shall make requests for approval to conduct research directly to the Director of SPY. A concept paper outlining the intended research should be forwarded directly to the Director of SPY.

    2. The Director of SPY shall be responsible for:

a. Presenting the research concept to the appropriate officials and administrative approval. The appropriate officials and administrative bodies shall include, but not necessarily limited to, the SPY Management Team, the Community Public Health Services Research Committee, and the Supervising Juvenile Court Judge.

b. Advising the Primary Care Administrator about the research concept.

c. Forwarding to the investigators(s) a decision regarding approval/disapproval of the concept paper within three (3) weeks from the date that the concept paper is received.

3. Upon receipt of the concept paper approval, the investigator(s) should proceed with development of a complete research proposal and steps for obtaining approval by the Committee on Human Subjects. The investigators(s) will be responsible for forwarding to the Director of SPY a completed research proposal, including Committee on Human Subjects approval and provisions for meeting the informed consent requirements described in II.B. below.

4. The investigator(s) may proceed with research only after the approval of the Director of SPY, the Chief Probation Officer, the Supervising Juvenile Court Judge, and the Committee on Human Subjects has been obtained. The investigator(s) will be responsible for forwarding to the Director of SPY semiannual progress reports and findings.

B. Participation of a juvenile in research or experiments, as described in I.A above, requires assent of the juvenile and the permission of his/her parents(s)/legal guardian unless there is basis for parental/legal guardian permission to be waived (45CFR 46.404, 46.405, 46.408). In any case in which the permission of a juvenile's parent(s)/legal guardian is waived, an alternate mechanism for protecting the juvenile shall be implemented in accordance with II.B.2 below.

1. Conditions under which the requirement of parental/legal guardian permission may be waived include the following:

a. The research is designed for conditions or for a subject population for which parental/legal guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children) [45 CFR 46.408 (c)]; or

b. In accordance with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research:

(1) The research is designed to identify factors related to the incidence or treatment of certain conditions in adolescents for which, in certain jurisdictions, the adolescents may legally receive treatment without parental permission (see III.C., "Specific Health Care Services for which Youth May Consent", in Policy No. 1434, "Consent for Health Care".)

(2) Research in which the subjects are "mature youth" (i.e., capable of giving informed consent) and the procedures involved entail essentially no greater than minimal risk that such individuals might reasonably assume on their own;

(3) Research designed to meet the needs of children designated by their parents as "in need of supervision" (generally the same as status offenders);

(4) Research involving children whose parents are legally or functionally incompetent.

2. If parental/legal guardian permission is waived, there must be an appropriate alternate mechanism for protecting the children and the choice of an appropriate alternate mechanism would depend upon the nature and purpose of the research activities, the risk and anticipated benefit to the subjects, and their age, maturity, status, and condition [45 CFR 46.408].

   Appropriate alternate mechanisms shall be determined on a case-by-case basis, but might include:

   a. Consent of a mature youth alone,

   b. Court approval, and

   c. Explanation of the research by a SPY Health Care Provider who is not associated with the research.

3. For a juvenile to participate in research studies or experiments, acquisition of assent of the juvenile and permission of his/her parents/legal guardian, as appropriate, shall be in accordance with the requirements for documentation of informed consent as outlined in 45 CFR 46.116 and 46.117. In addition, each juvenile shall be

informed in advance that his/her participation in the research/experiment is voluntary and confidential, and will not be communicated to the Probation Services, Juvenile Hall or Juvenile Court staffs.

C. Any staff member who receives a request for or observes an action which involves, or appears to involve, medical, pharmaceutical, or cosmetic experimentation using juvenile subjects shall report such contact and/or observations to his/her supervisor.

REFERENCES:

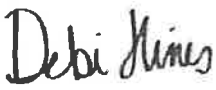
1. Protection of human subjects (45 CFR 46), revised January 15, 2009. In: Office for Protection from Research Risks Reports: Protection of Human Subjects. Bethesda, MD.: Office for Protection from Research Risks. National Institutes of Health, Public Health Service, Department of Health and Human Services.

2. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research: Research involving children: Report and recommendations. Washington, D.C.: National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; 1977. U.S. Department of Health, Education, and Welfare publication (OS) 77-0004; 17,18.

3. California Welfare and Institutions Code, Div. 1, ch.1, sec. 101. In: West's California Juvenile Laws and Court Rules-1991. St. Paul, MN: West Publishing Co.: 1991:11.

4. California Welfare and Institutions Code, Div. 2, pt.1, ch.2, art. 14, sec. 601. In: West's California Juvenile Laws and Court Rules-1991. St. Paul, MN: West Publishing Co.: 1991: 81.

SPECIAL PROGRAMS FOR YOUTH	Policy Number: 1.1454
Policy Title: Participation in Research Corresponds to: Title 15, Article 8, Section 1454	Written: 3/7/2013

Policy# 1454 Review date:	Approved by:  Digitally signed by Mona Tahsini Date: 2020.02.05 15:43:10 -08'00' Mona Tahsini, MFT Director, SPY  Helena Chan 2020.02.05 16:15:09 -08'00' Helena Chan, MD Behavioral Health Medical Director, SPY  Digitally signed by Debi Hines Date: 2020.02.26 11:38:02 -08'00' Debi Hines, RN Nurse Manager, SPY  Digitally signed by Luis Recinos Date: 2020.05.11 11:55:03 -07'00' Luis Recinos Director, Juvenile Justice Center Katherine Miller Chief Probation Officer, Juvenile Probation Department