

DEPARTMENT OF HEALTH SERVICES
COUNTY OF LOS ANGELES

SUBJECT: **PARAMEDIC TRIAL AND SCIENTIFIC STUDIES**

REFERENCE NO. 830

PURPOSE: To provide a uniform procedure for acquiring authorization to conduct research or to perform additional prehospital treatment procedures or administer additional drugs not currently a part of the paramedic scope of practice.

AUTHORITY: Health & Safety Code, Division 2.5, Sections 1797.221, 24170-24179.5
California Code of Regulations, Title 22, Division 9, Chapter 4, Section 100146
Federal Policy for the Protection of Human Subjects, DHHS Regulations 45 CRF 46, FDA Regulations-CRF Title 21

DEFINITION: For the purposes of this policy, a trial or scientific study is an evaluation or assessment of a study population in which a drug, device, assessment process, or treatment procedure intervention is introduced or withheld. Descriptive or observational studies that do not introduce or withhold a drug, device, assessment process, or treatment procedure are not defined as trials or scientific studies.

PRINCIPLES:

1. The Medical Director of the Emergency Medical Services (EMS) Agency may approve or conduct any trial or scientific study of the efficacy of the prehospital emergency use of any drug, device, or treatment procedure within the local EMS system, utilizing any level of prehospital emergency medical care personnel. The study shall be consistent with any requirements established by the State EMS Authority for trial or scientific studies conducted within the prehospital emergency medical care system, and, where applicable, with the California Health and Safety Code, Division 104, Part 5, Chapter 6, Article 5, Section 111550-111610.
2. No drug, device, or treatment procedure that is specifically excluded by the California EMS Authority from usage in the EMS system shall be included in a trial or scientific study without the approval of the EMS Agency Medical Director and the Director of the California EMS Authority.
3. No local EMS system field trial or scientific study shall be implemented prior to approval by the EMS Agency Medical Director.
4. All trial or scientific studies must be reviewed and approved by an appropriate institutional review board. This review should be in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and the U.S. Department of Health and Human Services Office of Human Research Protection.
5. Descriptive and observational studies that do not change or add procedures, drugs, assessment process, or invasive devices do not require approval of the EMS Agency Medical Director. Descriptive and observational studies not submitted for approval must

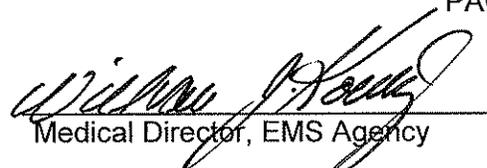
EFFECTIVE: 6-1-79

REVISED: 08-01-12

SUPERSEDES: 10-15-09

APPROVED:


Director, EMS Agency


Medical Director, EMS Agency

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- comply with all Federal and State statutes and regulation, including HIPAA. Failure to comply is the sole responsibility of the researcher(s) involved.
6. Any trial, scientific study, descriptive or observational study use of TEMIS or other data under the authority of, or maintained and managed by, the EMS Agency must be approved by the EMS Agency Director and Medical Director. Requests for use of such data must be made in writing to the EMS Agency.
 7. The Los Angeles County EMS Agency maintains a Federal-Wide Assurance (FWA) as required by the U.S. Department of Health and Human Services (DHHS) for the conduct of federally funded research. This FWA requires the Agency to comply with the requirements set forth in the Federal Policy for the Protection of Human Subjects (DHHS Regulations 45 CFR 46, FDA Regulations-CRF Title 21) and California Health and Safety Code (Sections 24170-24179.5).

POLICY:

- I. A research proposal must be accompanied by a research protocol which provides the following information:
 - A. A statement of the trial or study hypothesis or objectives.
 - B. A description of the procedure(s) or medication(s) proposed, the medical conditions for which they are to be utilized, and the patient population that will benefit.
 - C. A compendium of relevant studies and material from the medical literature.
 - D. A description of the proposed study design including the scope of the study and method of evaluating the effectiveness of the procedure(s) or medication(s) and expected outcome.
 - E. Recommended policies and procedures to be instituted by the EMS Agency regarding the use and medical control of the procedure(s) or medication(s) used in the study.
 - F. A description of the training and competency testing required to implement the study.
 - G. Procedures for obtaining patient consent or institutional review board verification that the trial or scientific study is exempt from requiring patient consent as outlined in current State and Federal regulations.
 - H. Appropriate institutional review board approval.
 - I. Statements of costs to patient or providers.
 - J. Statement of legal authority for the use of the proposed drug(s) or procedure(s).
 - K. Letters from provider agencies participating in the project indicating their willingness to participate.
 - L. Letters from hospitals participating in the project indicating review by their institutional review board and willingness to participate.

- II. Upon approval of a trial or scientific study, the sponsor shall:
- A. Notify all hospitals and appropriate private entities or political jurisdictions involved or affected by the research of the approval of the research.
 - B. Conduct training sessions for all agencies and personnel involved in the research, if necessary.
 - C. Submit a written report to the EMS Agency Medical Director every 6 months during the duration of the study to include the progress of the study, number of patients studied, beneficial effects and adverse reactions or complications.
 - D. Submit a written report to the EMS Agency Medical Director within 18 months of initiation of the study to include the progress of the study, number of patients studied, beneficial effects, adverse reactions or complications, appropriate statistical evaluation and general conclusions.
 - E. Immediately inform the EMS Agency Medical Director of any unanticipated adverse events or departure from the protocol, including discontinuation of the study, prior to its completion.
- III. The EMS Agency Medical Director shall:
- A. Notify the research proposer within 14 days of receiving the request for trial or scientific study that it was received and request any missing information.
 - B. Involve the Medical Council to assist with the evaluation and approval of the trial or scientific study, if warranted.
 - C. Submit the trial or scientific study proposal to the local EMS Agency Director for approval.
 - D. Submit the trial or scientific study proposal to the State EMS Authority for approval.
 - E. Notify the research proposer of approval or disapproval of the trial or scientific study by the State EMS Authority. Submit the research proposer's written study conclusions or progress report to the State EMS Commission (EMSC) within 18 months of the initiation of the drug, device, or procedure intervention. The conclusion or progress report should include, at a minimum, the study objective(s); number of patients studied; beneficial effects; adverse reactions or complications; appropriate statistical evaluation; and general conclusions.
 - F. If the trial or scientific study is extended beyond the initially-approved time frame, submit a final report to the State EMSC.
- IV. For any federally funded research conducted under the Los Angeles County EMS Agency FWA:
- A. The EMS Agency ensures prompt reporting to the appropriate Institutional Review Board (IRB); appropriate institutional officials; the head of any department or agency conducting or supporting the research (or designee); any applicable regulatory body; and the DHHS Office of Human Research Protections (OHRP) of any:

1. Unanticipated problems involving risks to subjects or others. A reportable problem is one that results in death; life-threatening situation; hospitalization or prolonged existing hospitalization; a persistent or significant disability/incapacity; or a congenital anomaly/birth defect associated with the research.
 2. Serious or continuing noncompliance with the federal regulations or the requirements or determination of IRBs overseeing the research. This noncompliance can include failure to obtain proper informed consent or failure to manage personal health information in a manner compliant with the Health Insurance Portability and Accountability Act (HIPAA).
 3. Suspension or termination of IRB approval.
- B. The EMS Agency will ensure that the IRB(s) designated under the FWA have established written procedures for:
1. Conducting IRB initial and continuing review (not less than once per year) or research, and reporting IRB findings to the investigator and the Agency;
 2. Determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review;
 3. Ensuring prompt reporting to the IRB of proposed changes in a research activity and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subjects.