

DEPARTMENT OF HEALTH SERVICES  
COUNTY OF LOS ANGELES

SUBJECT: **EMS PILOT AND SCIENTIFIC STUDIES**

REFERENCE NO. 830

**PURPOSE:** To provide a uniform procedure for acquiring authorization to conduct a pilot or a scientific study 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:**

**Pilot or Scientific Study:** For the purposes of this policy, a pilot or scientific study is an evaluation or assessment of a study population in which a medication, device, assessment process, or treatment procedure is introduced or withheld. Descriptive or observational studies that do not introduce or withhold a drug, device, assessment process, or treatment procedure using EMS systemwide data may require, at the discretion of the Emergency Medical Services (EMS) Agency Medical Director, a data use approval as per Ref. Nos. 622, 622.1 through 622.5 and/or Institutional Review Board (IRB) submission/approval prior to implementation.

**PRINCIPLES:**

1. All pilot or scientific studies must be submitted for review and approval by the EMS Agency Medical Director or designee prior to implementation.
2. The EMS Agency Medical Director may approve or conduct any pilot or scientific study of the efficacy of the prehospital emergency use of any medication, 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 California EMS Authority for pilot 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.
3. No medication, device, or treatment procedure that is specifically excluded by the California EMS Authority from usage in the EMS system shall be included in a pilot or scientific study without the approval of the EMS Agency Medical Director and the Director of the California EMS Authority.
4. All proposed pilot or scientific studies shall not be implemented prior to approval by the EMS Agency Medical Director.
5. If applicable, IRB review may be required for approval at the discretion of the EMS Agency Medical Director.
6. Any pilot, scientific study, descriptive or observational study using data or information

EFFECTIVE DATE: 06-01-79

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REVISED: 09-01-21

SUPERSEDES: 01-01-21

APPROVED:

  
Director, EMS Agency

  
Medical Director, EMS Agency

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 (refer to Ref. Nos. 622, 622.1 through 622.5).

**POLICY:**

- I. A pilot or scientific study proposal shall include the following information:
  - A. A letter of request addressed to the EMS Agency Medical Director which includes the following:
    1. A statement of the pilot or scientific study objective(s) and a description of the proposed procedure(s) or medication(s), the medical conditions for which they are to be utilized, and the target population
    2. Timeline for study implementation, and duration of the study based on anticipated uses/enrollment
    3. Specific, measurable outcome(s) that will be used to evaluate the success of the study
  - B. Study's outcome measure/data analysis which include:
    1. Quality improvement plan for evaluating efficacy and safety
    2. Defined outcome measures
    3. Data collection tool(s)
    4. Approved IRB application, applicable if intent to publish results of the study
  - C. 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, if necessary.
  - D. A description of the training and competency testing required to implement the study. The study should have a primary instructor who is knowledgeable, skilled and current in the subject matter of the educational material relevant to the proposed study.
  - E. Statement of costs to patient or providers.
  - F. Statement of legal authority for the use of the proposed drug(s) or procedure(s).
  - G. Letters from provider agencies participating in the study indicating their willingness to participate.
  - H. Letters from hospitals or approved alternate care sites (e.g., Sobering Centers or Psychiatric Urgent Care Centers) participating in the study indicating willingness to participate, and review by their IRB when applicable.
- II. Upon approval of a pilot or scientific study, the investigator shall:

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- A. In collaboration with the EMS Agency, notify all hospitals, EMS provider agencies, and appropriate private entities or political jurisdictions involved or affected by the study.
  - B. Conduct training sessions for all hospitals, EMS provider agencies and personnel involved in the study, if necessary.
  - C. Submit quarterly updates to the EMS Agency Medical Director on the progress of the study, number of patients studied, beneficial effects and adverse reactions or complications, and appropriate interim analysis, whenever applicable. The investigator(s) may be requested to present study results/findings to the Medical Advisory Council.
  - D. 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.
  - E. Provide the final results/data analysis to the EMS Agency at the conclusion of the study (and interim as determined by the EMS Agency Medical Director during the approval process) based on the agreed upon data analysis plan and target outcomes.
- III. The EMS Agency shall:
- A. Notify the study proposer within 14 days of receiving the request for pilot or scientific study that it was received and request any missing information.
  - B. Involve the Medical Advisory Council; Innovation, Technology, and Advancement Committee (ITAC); or any other relevant Specialty Care Center Advisory Committee to assist with the evaluation and approval of the proposed study, if warranted.
  - C. Notify the pilot or study proposer within forty-five (45) days from receipt of the complete pilot or study proposal of approval or denial of the proposed pilot or study.
  - D. If applicable, submit the pilot or scientific study proposal to the California EMS Authority for approval. The EMS Agency may request assistance from the study investigators to prepare the necessary materials for submission to the California EMS Authority.
  - E. Notify the research proposer of approval or disapproval of the pilot or scientific study by the California EMS Authority.
  - F. For research projects requiring state EMS Agency approval, submit the research proposer's written study conclusions or progress report to the California 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. If the trial or scientific study is extended beyond the initially-approved time frame, submit a final report to the California EMSC.

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- G. Discontinue a pilot or study for safety or other concerns at any time at the EMS Agency Medical Director's discretion.
- H. Provide a written conclusion based on the results of the pilot or study which will include one of the following:
1. Implementation: Suitable for systemwide implementation as directed by the EMS Agency Medical Director
  2. Optional Use: EMS provider agencies maintain responsibility for education, training, and oversight of product/procedure/innovation use
  3. Pilot: Require that an EMS provider agency continue a specified pilot period and continue to submit pilot study data to the EMS Agency on a quarterly basis
  4. Insufficient Data: There is insufficient data to support continuation of the study. Discontinuation of the study indefinitely. This conclusion may change with introduction of new/additional evidence.

## CROSS REFERENCE:

Prehospital Care Manual:

Ref. No. 204, **Medical Advisory Council**Ref. No. 205, **Innovation, Technology, and Advancement Committee (ITAC)**Ref. No. 622, **Release of EMS Data**Ref. No. 622.1, **Data Request and Levels of Support**Ref. No. 622.2, **Limited Data Set Information**Ref. No. 622.3, **Intended Use of Limited Data Set Information**Ref. No. 622.4, **Data Use Agreement**Ref. No. 622.5, **Confidentiality Agreement**