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 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 43.3, Article 2, Section 100091.02
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 of an intervention (i.e., medication, device, protocol, or other treatment) that is prospectively tested in a study population. Testing may include the introduction or withholding of the proposed intervention.

Investigator(s): The individual or team of individuals that is leading the pilot or scientific study.

Institutional Review Board: The Institutional Review Board (IRB) is a committee responsible for reviewing and approving all human subjects research to ensure the welfare of the participants is protected.

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 a pilot or scientific study evaluating the safety, feasibility, and/or efficacy of the prehospital medication, device, protocol, or other treatment within the local EMS system involving EMTs and/or paramedics. 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, protocol, or other treatment that is specifically excluded by the California EMS Authority from use in the EMS system shall be included in a pilot or scientific study without the approval of the EMS Agency Medical Director and the California EMS Authority.

4. Any pilot or scientific study using data or information under the authority of, or maintained and managed by, the EMS Agency must be approved by the EMS Agency Director and Medical Director prior to implementation.

APPROVED: Richard Tadeo
Director, EMS Agency

Medical Director, EMS Agency

5. When applicable, IRB approval will be required prior to implementation of a pilot or scientific study at the discretion of the EMS Agency Medical Director.

6. Requests for implementation of procedures and/or medications currently approved for local additional scope or optional use within Los Angeles County are not subject to this policy. Such requests will be processed as identified per Los Angeles County Scope of Practice policies (Ref. No. 802 and 803) and applicable approved unit inventory policies.

POLICY:

I. An investigator shall include the following information in a pilot or scientific study proposal submitted to the EMS Agency Medical Director:

   A. Background material on the proposed intervention (i.e., relevant studies or other medical literature).

   B. Statement of the pilot or study objective(s).

   C. Proposed timeline and duration for the pilot or scientific study.

   D. Description of the proposed intervention including medical conditions for which it will be used and the patient population that may benefit.

   E. Description of the proposed pilot or scientific study design and the method for evaluating the effectiveness and the safety of the intervention.

   F. Description of the data collection process.

   G. Description of specific and measurable outcome(s) to evaluate safety, feasibility, and/or efficacy of the intervention.

   H. Plan for quarterly reports that detail the descriptive characteristics and outcomes (safety and effectiveness) that will be collected and reported.

   I. Recommended policies and procedures to be instituted by the EMS Agency regarding the use and medical control of the intervention used, if necessary.

   J. A description of the training and competency testing required to implement the study. The pilot or scientific study should have a primary instructor who is knowledgeable, skilled and current in the subject matter relevant to the educational material for the proposed pilot or scientific study.

   K. Statement of ~~costs~~ anticipated risks and potential benefits to patient and/or EMS personnel.

   L. Statement of legal authority for the use of the proposed intervention.

   M. Letters from provider agencies participating in the pilot or scientific study indicating their willingness to participate.

   N. Letters from partner entities indicating willingness to participate, when applicable. Review by participating entities local IRB may also be required in some cases.

   O. IRB approval when applicable. If there is intent to publish the pilot or scientific

study results, an approved IRB is required. In addition, an IRB may be required based on the proposed study design and estimated risk to the patient or EMS personnel.

II. An investigator shall also submit a data use request if there is intent to use data that are maintained or managed by the EMS Agency as part of the pilot or scientific study (Refer to Ref. Nos. 622, 622.1 through 622.5).

III. An investigator shall adhere to the following stipulations after submission:

A. Allow up to 14 business days after proposal submission to receive notification from the EMS Agency of receipt of the proposal.

B. Provide any missing required information and resubmit study proposal revisions as requested by the EMS Agency Medical Director.

C. Allow up to 45 business days after EMS Agency receipt of a complete proposal to receive notification of approval or denial. Expect up to a total of 60 business days between complete study proposal submission and the EMS Agency approval/denial notification.

D. Refrain from commencing any pilot or scientific study activities (including training) until approval has been granted by the EMS Agency.

IV. An investigator shall adhere to the following requirements if pilot or scientific study approval is granted:

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 those involved in the study including all hospitals, EMS provider agencies, and personnel as applicable.

C. Submit quarterly reports, within 30 days of the end of the quarter, to the EMS Agency Medical Director on the progress of the study, number of patients enrolled/treated, descriptive characteristics, and safety and effectiveness outcomes with appropriate interim analysis when applicable.

D. Share pilot or scientific study reports with the Medical Advisory Council when requested.

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.

F. Provide the final report 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.

V. The EMS Agency responsibilities are the following:

A. Notify the study proposer within 14 business days of receiving the request for pilot or scientific study that it was received and if necessary, 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 investigator within forty-five (45) days from receipt of the complete proposal of approval or denial of the proposed pilot or scientific study, or for the need for approval by the California EMS Authority.

D. In cases where California EMS Authority approval is required, including for pilots or scientific studies where Local Optional Scope of Practice approval is required, the EMS Agency will work with the investigator to submit the pilot or scientific study proposal to the California EMS Authority for approval. Study investigators are responsible for preparing the necessary materials for submission to the California EMS Authority. The EMS Agency will further:

   a. Assist with submission of a request for Local Optional Scope of Practice, when applicable.

   b. Notify the investigator of approval or disapproval of the pilot or scientific study by the California EMS Authority.

   c. Submit the investigator's written study conclusions or progress report to the California EMS Commission (EMSC) within 18 months of the initiation of the pilot or scientific study 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.

E. Discontinue a pilot or scientific study for safety or other concerns at any time at the EMS Agency Medical Director's discretion.

F. Provide a written conclusion based on the results of the pilot or scientific 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 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**
Ref. No. 802, **Emergency Medical Technician (EMT) Scope of Practice**
Ref. No. 803, **Los Angeles County Paramedic Scope of Practice**