SAN FRANCISCO EMERGENCY MEDICAL SERVICES AGENCY

PILOT RESEARCH STUDIES & EMS DATA USE
EMSAC FEBRUARY 2026

EFFECTIVE DATE: xx/xx/xx *POLICY REFERENCE NO: 6030* *SUPERSEDES: 8/1/08*

1. PURPOSE

1.1. To provide a uniform procedure for requesting release of EMS data.

1.2. 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.

2. DEFINITION

2.1. Covered Entities: Healthcare providers, health plans, and healthcare clearing houses that electronically transmit health information

2.2. Health Insurance Portability and Accountability Act (HIPAA): A federal law passed in 1996, which established a set of national standards for the electronic transmission of health information, including research subjects. Covered entities are required to comply with HIPAA regulations.

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

2.4. 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

2.5. Limited Data Set Information: Information that does not include standard identifiers so as to ensure that remaining health information is not identifiable to an individual. Individual identifiers include but are not limited to the following: names, postal address (other than city, state and zip code), dates of birth, telephone number, social security numbers, medical record numbers.

2.6. 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.

2.7. Protected Health Information (PHI): Individually identifiable health information that is held or transmitted in any form or media, whether electronic, written, spoken, printed, digital, recorded, or photographic, which can be linked to an individual, or there is reasonable basis to believe it can be used to identify an individual.

3. POLICY – EMS DATA USE

3.1. EMS data contains patient information which is protected under HIPAA. Without specific authorization, the EMS Agency will only release Limited Data Set Information

3.2. Local EMS stakeholders and healthcare researchers are encouraged to utilize EMS data to evaluate patient care and outcomes and to answer other healthcare related questions that may lead to system improvements. Research studies will require approval prior to data release from the appropriate IRBs.

3.3. All release of data will be approved by the Director of the EMS Agency (or designee). When applicable, the EMS Agency will seek the recommendation of the appropriate EMS Research Subcomittee.

4. PROCEDURE- EMS DATA USE

4.1. Requesting party will submit a **SF EMSA data use agreement**

4.2. EMSA will review request and inform the requesting party of the the approval/modification request(s)/disapproval decision within 4 weeks of receiving the request.

4.3. **If approved** EMSA will:

4.3.1. Prepare the data in the agreed upon format. If the data format has not been specified by the requesting party, an appropriate format will be utilized (i.e., graph, tables, etc.)

4.3.2. Release the data following receipt of IRB approval, if applicable, and approval by the Director of the EMS Agency (or designee)

5. POLICY- PILOT OR SCIENTIFIC STUDY

5.1. All pilot or scientific studies must be submitted for review and approval by the EMS Agency Medical Director or designee prior to implementation.

5.2. 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

5.3. 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.

5.4. 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. PROCEDURE- PILOT OR SCIENTIFIC STUDY

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

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

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

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

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

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

6.1.6. Description of the data collection process

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

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

6.1.9. 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.

6.2. Investigators shall adhere to the following **after submission**:

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

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

6.2.3. 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

6.3. Investigators shall adhere to the following **if study approved**:

6.3.1. 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

6.3.2. Conduct training sessions for those involved in the study including all hospitals, EMS provider agencies, and personnel as applicable

6.3.3. Share pilot or scientific study reports with the EMS Research Subcomittee as requested

6.3.4. 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

6.3.5. 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

6.4. EMS Agency responsibilities are the following:

6.4.1. Notify the study proposer within fourteen (14) business days of receiving the request for pilot or scientific study that it was received and if necessary, request any missing information

6.4.2. 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

6.4.3. 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

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

7. AUTHORITY

7.1. California Health & Safety Code, Division 2.5, Section 1797.221

7.2. California Code of Regulations, Title 22, Division 9, Sections 10064.1 and 100146

7.3. Confidentiality of Medical Information Act, California Civil Code Sections 56-56.16

7.4. California Health and Safety Code, Division 104, Part 5, Chapter 6, Article 5, Section 111550-111610

~~8. POLICY~~

~~**8.1.** Study Protocol~~

~~**8.1.1.** The EMS Agency Medical Director must approve the study protocol of any EMS research study in the San Francisco EMS System prior to implementation of the research study.~~

~~**8.2.** The Principal Investigator of an EMS study shall submit a copy of the study protocol to the EMS Agency Medical Director prior to the initiation of the study. The study protocol shall consist of the following sections:~~

~~**8.2.1.** Background/Significance~~

~~**8.2.2.** Methods~~

~~**8.2.3.** Study Subjects~~

~~**8.2.4.** Data Collection and Analysis~~

~~**8.2.5.** Consent Process~~

~~**8.2.6.** Training and competency testing required to implement the study~~

~~**8.2.7.** Recommended policies and procedures to be instituted regarding the use and medical control of the procedures or medication used in the study.~~

~~**8.2.8.** Risks/Benefits~~

~~**8.2.9.** Confidentiality/Data Security/HIPAA Compliance~~

~~**8.2.10.** References, including copies of relevant literature~~

~~**8.3.** Processing by the EMSA~~

~~**8.3.1.** Any studies involving the EMS system are to be submitted to the EMS Agency prior to seeking Institutional Review Board (IRB) approval.~~

~~**8.3.2.** For studies limited to record reviews, the EMS Agency will aim to render a decision to approve or disapprove the study within 21 days of receipt.~~

~~**8.3.3.** For studies involving changes in paramedic practice or Trial Studies, the EMS Medical Director will appoint a Research Advisory Working Group of qualified persons with experience in research and knowledge of the effect of the proposed research on the EMS system. The committee will assist the Medical Director with the approval of the study and will aim to render a decision to approve or disapprove the study within 45 days of receipt.~~

~~**8.3.4.** For Trial Studies requiring State EMS Authority Approval, the Principal Investigator will need to allow an additional 45 days for the entire review process (refer to Section IV, E of this policy).~~

~~**8.4.** Institutional Review Board Approval~~

~~**8.4.1.** The Principal Investigator shall submit a copy of the IRB protocol approval or exemption to the EMS Agency Medical Director prior to the initiation of the study.~~

~~**8.4.2.** The protocol of an EMS study in the City and County of San Francisco must comply with the following~~

8.4.2.1. All federal requirements for the protection of human subjects in research (45 CFR 46 and 21 CFR 56).

8.4.2.2. Procedures for application to and review by the sponsoring institution's IRB.

8.4.2.3. The requirements set by the State of California EMS Authority (CCR, Title 22, Section 100144 subsection (b) (14), if intending to perform any prehospital emergency medical treatment or procedure which is additional to the Paramedic Scope of Practice (refer to Section IV, E of this policy).

8.5. EMS Authority Request for Approval of Trial Studies

8.5.1. The Principal Investigator shall complete State EMS Authority Form #0391 and submit to the EMS Agency Medical Director for review.

8.5.2. The EMS Agency Medical Director will forward the request to the State EMS Authority.

8.6. Study Implementation

8.6.1. For studies that involve patient interventions by prehospital personnel, the Principal Investigator must ensure the following:

8.6.1.1. A certified EMT and/or licensed and accredited paramedic is either a study investigator, coordinator or liaison to provide input on the study protocol. (EMT and/or paramedic from the local EMS System is preferred);

8.6.1.2. A regular review of study progress with the prehospital personnel through quarterly newsletters, direct feedback and/or meetings.

8.7. The EMS Agency Medical Director may revoke approval of the project for violations of patient's rights or for activities and procedures not specified in the proposal.

8.8. Data Collection and Release of Medical Record Information

8.8.1. Ambulance Providers

8.8.1.1. The principal investigator shall develop the mechanism for obtaining data from the ambulance providers.

8.8.2. Base Hospital

8.8.2.1. The principal investigator shall identify a process for collecting data from the Base Hospital.

8.8.3. Receiving Hospitals

8.8.3.1. The study protocol will address the specific mechanisms for obtaining patient consent and for maintaining patient confidentiality.

8.8.3.2. A copy of the study protocol will be included with the letter to hospitals requesting participation in the research study.

8.8.3.3. If the hospital consents to participate in an EMS research study, a hospital liaison will facilitate medical records retrieval according to the hospital's internal procedures and policies.

8.9. Study Results

8.9.1. Quarterly written reports will be submitted to the EMS Agency Medical Director. These reports are to include:

8.9.1.1. Brief summary of project;

8.9.1.2. Objectives of study;

8.9.1.3. Results to date;

8.9.1.4. Adverse events or safety issues

8.9.1.5. Logistical problems

8.9.1.6. Work plan for the upcoming quarter, and

8.9.1.7. Conclusions.

8.9.2. Copies of the annual progress report to the IRB will be submitted to the EMS Agency Medical Director.

8.9.3. Copy of the annual research renewal notice from the IRB.

8.9.4. Copies of reports from any safety monitoring committees involved in oversight of the research study.

8.9.5. The EMS Medical Director may request that the Principal Investigator provide a presentation on the progress of the study to EMS Advisory Committee.

8.10. The Principal Investigator shall submit a final written report to the EMS Agency Medical Director at the conclusion of the study. A copy of any abstracts or manuscripts submitted for publication will be provided, in confidence, at the same time to the EMS Agency Medical Director.