SAN FRANCISCO EMERGENCY MEDICAL SERVICES AGENCY

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RESEARCH STUDIES

I. PURPOSE

A. To ensure that all public and non-profit private entities, scientific institutions, and individuals engaged in the conduct of EMS research in the San Francisco Emergency Medical Services (EMS) system adhere to a standardized procedure and review process.

II. AUTHORITY

A. California Health & Safety Code, Division 2.5, Section 1797.221
B. California Code of Regulations, Title 22, Division 9, Sections 10064.1 and 100146
C. Confidentiality of Medical Information Act, California Civil Code Sections 56-56.16

III. REFERENCE

A. EMSA #125 Guidelines for EMT 797.221 Paramedic Scope of Practice: Request for Additions to the EMT-P Scope of Practice

IV. POLICY

A. Study Protocol

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.

B. 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:

1. Background/Significance
2. Methods
3. Study Subjects
4. Data Collection and Analysis
5. Consent Process
6. Training and competency testing required to implement the study
7. Recommended policies and procedures to be instituted regarding the use and medical control of the procedures or medication used in the study.
8. Risks/Benefits
9. Confidentiality/Data Security/HIPAA Compliance
10. References, including copies of relevant literature

C. Processing by the EMSA

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

D. Institutional Review Board Approval

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.
2. The protocol of an EMS study in the City and County of San Francisco must comply with the following:
    a) All federal requirements for the protection of human subjects in research (45 CFR 46 and 21 CFR 56).
    b) Procedures for application to and review by the sponsoring institution's IRB.
    c) 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).

E. EMS Authority Request for Approval of Trial Studies

1. The Principal Investigator shall complete State EMS Authority Form #0391 and submit to the EMS Agency Medical Director for review.
2. The EMS Agency Medical Director will forward the request to the State EMS Authority.

F. Study Implementation

1. For studies that involve patient interventions by prehospital personnel, the Principal Investigator must ensure the following:
    a) 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);

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

G. 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.

H. Data Collection and Release of Medical Record Information

1. Ambulance Providers
   a) The principal investigator shall develop the mechanism for obtaining data from the ambulance providers.
2. Base Hospital
   a) The principal investigator shall identify a process for collecting data from the Base Hospital.
3. Receiving Hospitals
   a) The study protocol will address the specific mechanisms for obtaining patient consent and for maintaining patient confidentiality.
   b) A copy of the study protocol will be included with the letter to hospitals requesting participation in the research study.
   c) 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.

I. Study Results

1. Quarterly written reports will be submitted to the EMS Agency Medical Director. These reports are to include:
   a) Brief summary of project;
   b) Objectives of study;
   c) Results to date;
   d) Adverse events or safety issues
   e) Logistical problems
   f) Work plan for the upcoming quarter, and
   g) Conclusions.
2. Copies of the annual progress report to the IRB will be submitted to the EMS Agency Medical Director.
3. Copy of the annual research renewal notice from the IRB.
4. Copies of reports from any safety monitoring committees involved in oversight of the research study.
5. The EMS Medical Director may request that the Principal Investigator provide a presentation on the progress of the study to EMS Advisory Committee.

J. 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.