Monterey County EMS System Policy

Policy Number: 6160
Effective Date: 7/1/2024
Review Date: 6/30/2027

RESEARCH STUDIES

I. PURPOSE

To ensure that all public and non-profit private entities, scientific/training institutions, and individuals engaged in the conduct of EMS research in the Monterey County EMS system adhere to a standardized procedure and review process.

II. POLICY

A. The EMS Agency Director and Medical Director must approve the study protocol of any EMS research study in the Monterey County 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 initiation of the research 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. Conflicts of Interest, to minimally include conflicts identified in 21 CFR 54.1, 21 CFR 54.2, 21 CFR 54.4, 21 CFR 312.64(d), and 21 CFR 812.110(d)
11. References, including copies of relevant literature

C. Processing by the EMS Agency

1. Any studies involving the Monterey County 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 twenty-one (21) days of receipt.
3. For studies involving changes in paramedic practice or Trial Studies, the EMS Medical Director may 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 forty-five (45) days of receipt.
4. For Trial Studies requiring CA EMS Authority (EMSA) approval, the Principal Investigator will need to allow an additional forty-five (45) days for the entire review process (refer to Section IV, E of this policy).

D. Institutional Review Board (IRB) 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 Monterey County 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 CA EMSA (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. Request for CA EMSA Approval of Trial Studies

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

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 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. Communication Centers

   The Principal Investigator shall identify a process for collecting data from involved Communication Centers.

2. First Responders

   The Principal Investigator shall identify a process for collecting data from First Responders.

3. Ambulance Providers

   The Principal Investigator shall develop the mechanism for obtaining data from Ambulance Providers.

4. Hospitals/Base Hospital

   The Principal Investigator shall identify a process for collecting data from Hospitals/Base Hospitals.

5. 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. The Principal Investigator will submit quarterly written reports to the EMS Agency Medical Director. These reports shall 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. The Principal Investigator shall also submit the following to the EMS Agency Medical Director:

   a. The annual progress report to the IRB.

b. The annual research renewal notice from the IRB.

c. Reports from any safety monitoring committees involved in oversight of the research study.

5. The EMS Agency Medical Director may request that the Principal Investigator provide a presentation on the progress of the study to Clincal Care Committee (CCC).

6. 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.

END OF POLICY

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