TITLE: **RESEARCH STUDIES** EMS Policy No. **6680**

PURPOSE:

To ensure that all public and non-profit private entities, scientific institutions, and individuals engaged in conducting patient care related EMS research within the San Joaquin County Emergency Medical Services (EMS) system adhere to a standardized procedure and review process.

AUTHORITY:

California Code of Regulations, Title 22, Division 9, Sections 10064.1 and
California Health and Safety Code, Division 2.5, Section 1797.221

POLICY:

I. Approval
   A. All patient care related EMS research conducted in the San Joaquin County EMS System must be approved by the EMS Medical Director.
   B. The principal investigator of an EMS study shall submit a copy of the study protocol to the EMS Medical Director prior to the initiation of the study. The study protocol shall consist of the following elements:
      1. Background/Study Significance
      2. Methods
      3. Study Subjects
      4. Data Collection and Analysis
      5. Consent Process
      6. Risks/Benefits
      7. Confidentiality
      8. References

II. Institutional Review Board (IRB) Approval
   A. The principal investigator shall submit a copy of the IRB approval or exemption and the IRB approved study protocol to the EMS Medical Director prior to initiation of the study.
   B. The study protocol of an EMS study in San Joaquin County must comply with the following:
      1. All federal requirements for the protection of human subjects in research (45 CFR 46 and 21 CFR 56).
      2. Procedures for application to and review by the sponsoring institution's IRB.
      3. The requirements set by the State of California Emergency Medical Services Authority (EMSA) (CCR, Title 22, Section 100144, subsection

Approved: Signature on File
Medical Director

Signature on File
EMS Administrator

(b) (14)), if intending to perform any prehospital emergency medical treatment or procedure which is additional to the Paramedic Scope of Practice.

III. Study Implementation
- A. For studies that involve patient interventions by prehospital personnel, the principal investigator must ensure the following:
  1. A certified EMT, licensed and accredited paramedic, and/or authorized MICN is a study investigator, coordinator, or liaison to provide input on the study protocol.
  2. A regular review of study progress with the prehospital personnel through quarterly reports and direct feedback or meetings.

IV. Patient Rights Violations
- A. The EMS Medical Director may revoke approval of any research study for violations of patient rights or for activities not specified in the written and approved proposal.

V. Data Collection and Release of Medical Records
- A. Ambulance Providers: The principal investigator shall develop the mechanism for obtaining data from the ambulance providers.
- B. Base Hospitals: The principal investigator shall identify a process for collecting data from the Base Hospital.
- C. Receiving Hospitals
  1. The study protocol will address the specific mechanisms for obtaining patient consent and for maintaining patient confidentiality.
  2. A copy of the study protocol will be included with the letter to hospitals requesting participation in the research study.
  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.

VI. Study Results
- A. Quarterly written reports will be presented to the EMS Medical Director or designee.
- B. The principal investigator shall submit a final written report to the EMS Medical Director at the conclusion of the study. A copy of the manuscript for publication may be submitted in lieu of a final report.