

General Policy and Procedure

Research With EMS Involvement

Any pre-hospital or interhospital involvement in a research study will require approval of the Medical Control Board prior to any EMS participation. This applies to any study which requires participation by base station or EMS personnel, or which influences the patient's destination or treatment.

Procedure:

All studies will be initially presented to the Data and Evaluation Subcommittee (D&E) which will review the study and pass their recommendations to the Medical Control Board.

The following material must be submitted in writing to the D&E Subcommittee. Researchers are welcome to present their studies in person, but if the required items are not included in the D&E Subcommittee agenda packet for the meeting, the D&E Subcommittee will defer their recommendation until the following D&E Subcommittee meeting. This will permit adequate analysis of the study and its impact.

After receipt and analysis of the below items, the D&E Subcommittee will form recommendations concerning the study and carry them to the Medical Control Board.

- A. Complete research protocol including the inclusion and exclusion criteria.
- B. The institutions and providers within the MCA participating in the study.
- C. The researchers projection of the role of the provider or base station personnel in the study.
- D. The purpose of involving the base station or patient care providers in the study.
- E. Estimation by the researcher of the time which will be required by the patient care providers or base station personnel per case enrolled, and whether this is anticipated to delay any treatment or transport.
- F. Clarification as to whether participation will be automatic or elective on a case by case basis.
- G. Proposed duration of the study and total number of patients anticipated to be involved (estimated and as pertaining to pre-hospital or interhospital components of the study).
- H. Letters of support from the relevant hospitals/departments/agencies and providers.
- I. Report by three D&E approved paramedics, and/or base station personnel, and/or helicopter personnel specifically addressing their perceived role in the study, the time required per call to participate in the study and an estimation as to any delay in treatment or transport that participation in the study will entail. The chair of the D&E Subcommittee is responsible for selecting the approved personnel.
- J. Approval by an institutional review board at the discretion of the D&E Subcommittee.
- K. Any additional material for clarification deemed necessary by the D&E Subcommittee to form their recommendations.
- L. The D&E Subcommittee may require periodic progress reports. Continuation of MCA participation will be based on the recommendation of the D&E Subcommittee.

MCA Approved	11/96			
Implement	10/97			