EMS RESEARCH, PILOT PROJECTS, OR EXPANSION OF SCOPE OF PRACTICE

IDEA ¹

Draft Proposal ²


If any Answer YES

Draft Proposal Submitted to DOH EMSO

New EMS Concept? Scientific verification of existing EMS concept (including retrospective review) with possibility of being published? OR may interfere with any existing trial?

If any Answer YES

See Research Algorithm

If All Are NO

DOH EMSO notification suggested & may require approval from Animal Care & Use Committee or IRB

Need to assess logistics in PA

If All Are NO

See New Drug / Devices / Technique Algorithm

If YES

See Pilot Project Algorithm

¹ This idea can come from an individual, EMS service, EMS Region or related entity.
² Early contact with Regional Council(s) and Department of Health EMS Office is suggested.
RESEARCH ALGORITHM

Draft Research Proposal

Project involves any change from usual patient care or procedure?

YES

DOH EMSO

NO

PEHSC MAC for recommendations

Regional MAC(s) for recommendations

Investigator Considers Revision Based Upon MAC / DOH EMSO Recommendations

DOH EMSO

Investigator Receives IRB Approval

EMSO Approves

Study Conducted

Results to EMSO

Results reported to PEHSC MAC & regional MAC (s)

3a Proposal must have responsible principal investigator, letter(s) of support from EMS Services involved, letter(s) of support from service medical directors/medical command facilities (if appropriate), background/introduction, statement of hypothesis, description of methodology, estimated duration of the investigation, analysis of patient/volunteer/EMS personnel risks/complications/side effects, assurance of patient confidentiality, informed consent procedures, plan for notification of EMS Office of unexpected adverse results, and plan for providing the Department with progress reports and final reports.

4 Councils send recommendations to the PA Department of Health EMS Office within sixty days of receipt of the proposal. This is required before the EMS Office is permitted to give its approval.

5 Approval from the investigator’s IRB or PA state IRB is required before Department of Health EMS Office approves. The investigator may obtain IRB approval before or after MAC and DOH recommendations, but all revision must have IRB approval before DOH approval.

6 Department of Health EMS Office must respond to primary investigator within thirty days of receiving PEHSC and Regional MAC recommendations.

7 DOH EMSO notifies investigator, PEHSC and region(s) of approval.
NEW DRUG / DEVICE / TECHNIQUE APPROVAL PROCESS

PROPOSAL INCLUDING:
- Background of use in EMS
- Clinical need for advice, drug, and/or technique
- Specifications for use:
  • Indications
  • Restrictions
  • Adverse Effects
  • Contraindications
- Training Module

DOH EMSO

PEHSC MAC for recommendations

DOH EMSO Consideration of Approval & Addition to Scope of Practice

If Approved

Publication in PA Bulletin
Proposal must have responsible principal investigator, letter(s) of support from EMS Services involved, letter(s) of support from service medical directors/medical command facilities (if appropriate), background including previous use in EMS/introduction, statement of hypothesis, description of methodology, estimated duration of the investigation, analysis of patient/volunteer/EMS personnel risks/complications/side effects, assurance of patient confidentiality, informed consent procedures, plan for notification of EMS Office of unexpected adverse results, plan for providing the Department with progress reports and final reports, and must also include a CE training module for in service of EMS personnel.

4 Must send recommendations to the PA Department of Health EMS Office within sixty days of receipt of the proposal. This is required before the EMS Office is permitted to give its approval.

6 Department of Health EMS Office must respond to primary investigator within thirty days of receiving PEHSC and Regional MAC recommendations.