DEPARTMENT OF HEALTH
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RC- 2002-034

DATE: September 3, 2002

SUBJECT: Submission Process: EMS Research, Pilot Projects, or Expansion of Scope of Practice

TO: Regional EMS Directors

THRU: Director
EMS Office

FROM: Kathy Robinson
EMS Planning and Clinical Systems Manager

The attached four algorithms (flowcharts) are provided as a reference to outline the process for the submission of EMS research, pilot projects, or expansion of the EMS scope of practice to meet the policy requirements of 28 Pa. Code § 1001.61. None of the algorithms are intended as a "stand alone" reference. Potential investigators should be instructed to refer to page 1 of 4 for initial guidance in determining the "pathway" for an idea. Page 1 applies to EVERY proposal. To determine if a study meets the criteria of "research" or "pilot project," investigators will be required to provide clear scientific evidence (above that which is supplied by the manufacturer) that a device or clinical protocol is safe and effective for PREHOSPITAL use. A proposal must strongly document this evidence or it will not meet the criteria for a pilot project. If it does not meet the criteria for a pilot project, it must be submitted as a research project. An example of a research project might be the introduction of a new cardiac medication effective in cardiac catheterization labs to treat an arrhythmia but never studied in the prehospital setting. An example of an actual pilot project is the use of EpiPens®, a medication/product that is commonly used by laypersons with a history of anaphylaxis, as a primary medication for use by EMTs.

Although MOST proposals will need to be evaluated through the pilot project or research process, occasionally a drug, device, or scope of practice procedure may be proposed to the EMS Office with such convincing evidence that the investigative requirements of these guidelines are unnecessary for implementation. Such proposals will still be subjected to the review process as outlined on the New Drug/Device/Technique algorithm on page 3. Investigators are strongly encouraged to discuss such proposals with the EMS Office prior to submission for guidance on the proper pathway. The manager for EMS Planning and Clinical Systems is the point of contact for this purpose.

Please note: Proposals submitted as pilot projects or proposals for a new drug, device, or technique that do not meet the standard for scientific verification as "safe" for out-of-hospital use will be returned to investigators. These projects can be resubmitted as a research proposal using the research proposal algorithm.

The following chart summarizes the requirements for proposal submission:

PROPOSAL REQUIREMENTS	RESEARCH PROPOSAL	PILOT PROJECT
Statement of hypothesis	YES	YES
Description of methodology	YES	YES
Estimated duration of the investigation	YES	YES
Analysis of patient/volunteer/EMS risks/complications, side effects	YES	YES
Assurance of patient confidentiality	YES	YES
Informed consent procedures	YES	YES
Plan for the notification of the EMS Office of unexpected adverse results	YES	YES
Letter from the researcher who identifies him/herself as the lead investigator	YES	YES
Letter from the physician who assumes clinical responsibility for the investigation	YES	YES
Letters of support from EMS services involved	YES	YES
Letters of support from service medical directors/medical command facilities, as appropriate	YES	YES
Background including previous use in EMS	YES	YES
IRB approval	YES	NO
Training module for inservicing EMS personnel	NO	YES

Submit proposals to Kathy Robinson, EMS Planning and Clinical Systems Manager, PA Department of Health, Division of Emergency Medical Services, PO Box 90, Harrisburg, PA 17108.

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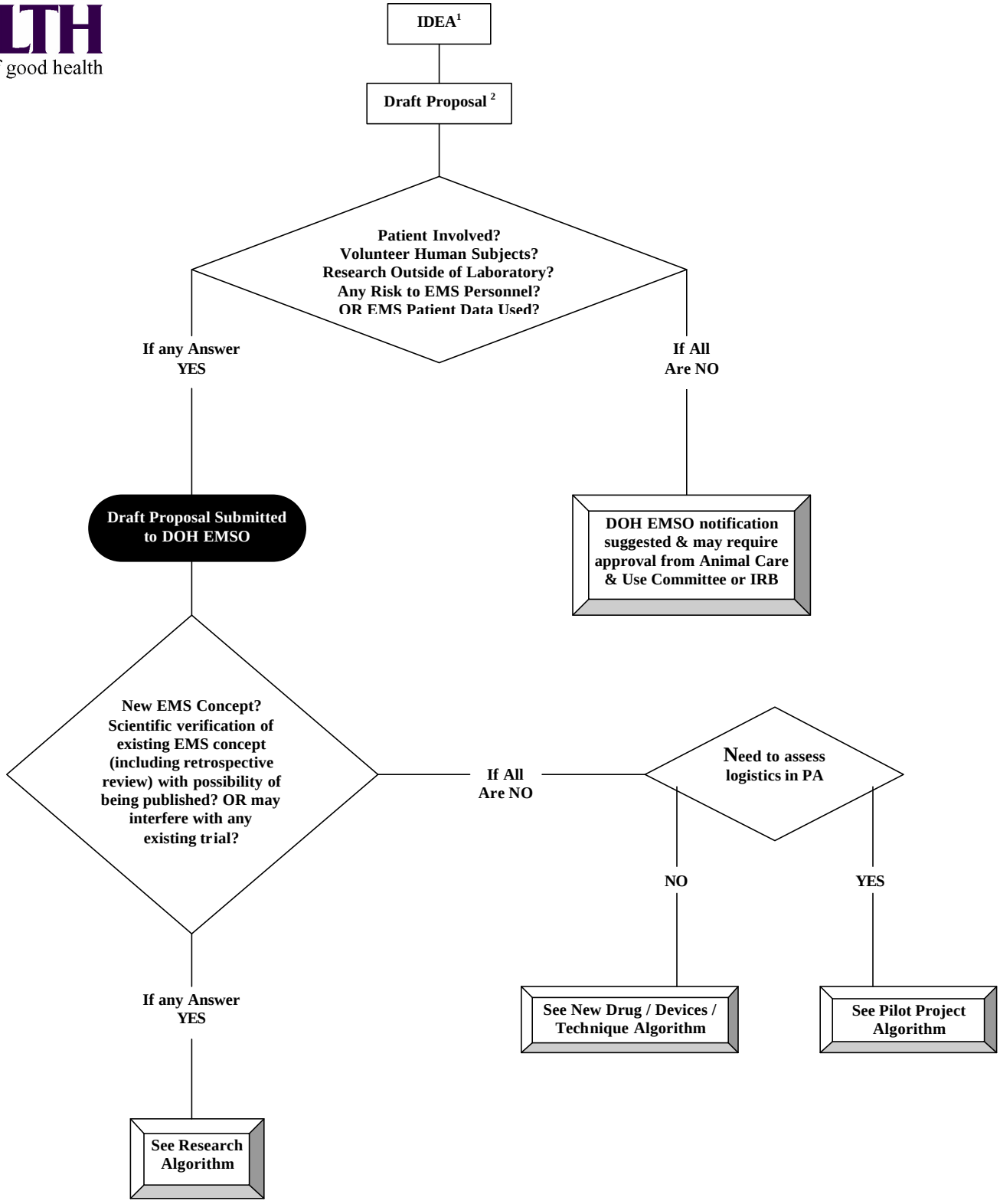
PROPOSED EMS RESEARCH, PILOT PROJECTS, OR EXPANSION OF SCOPE OF PRACTICE



[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.

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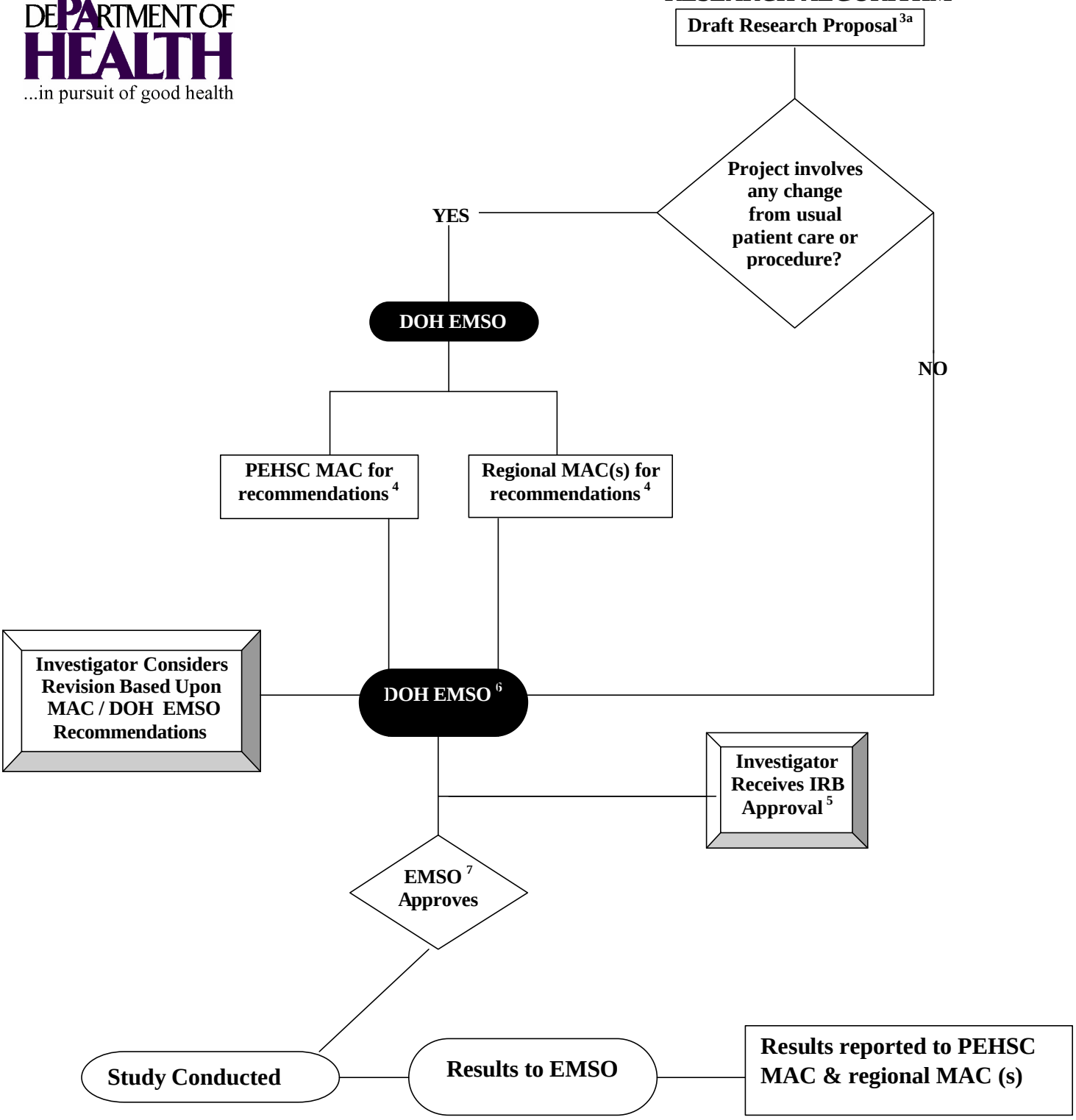
RESEARCH ALGORITHM



[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.

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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**

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DOH EMSO

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PEHSC MAC for recommendations

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DOH EMSO Consideration of Approval & Addition to Scope of Practice

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If Approved

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Publication in PA Bulletin

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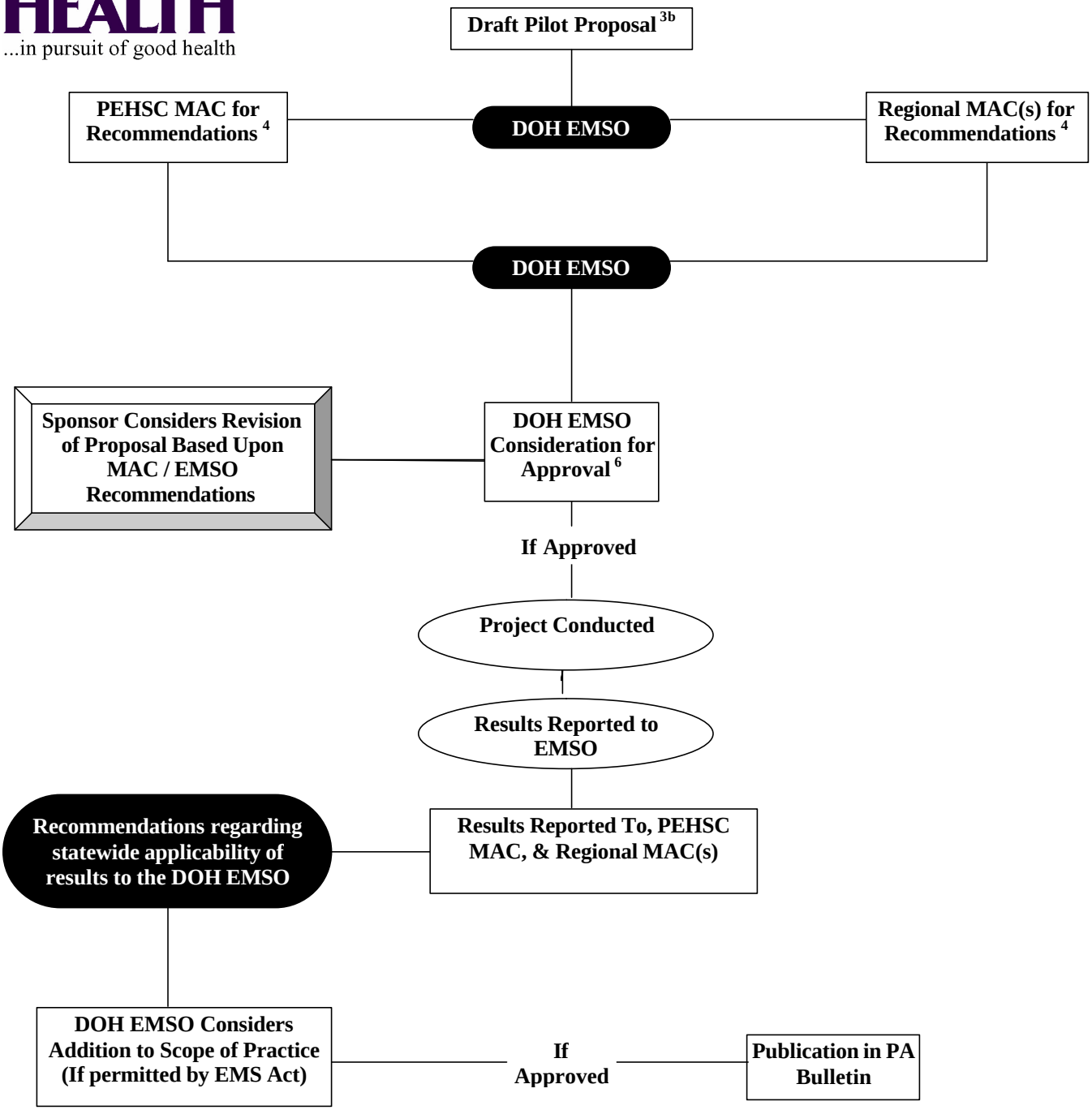
PILOT PROJECT ALGORITHM



[3b] 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.