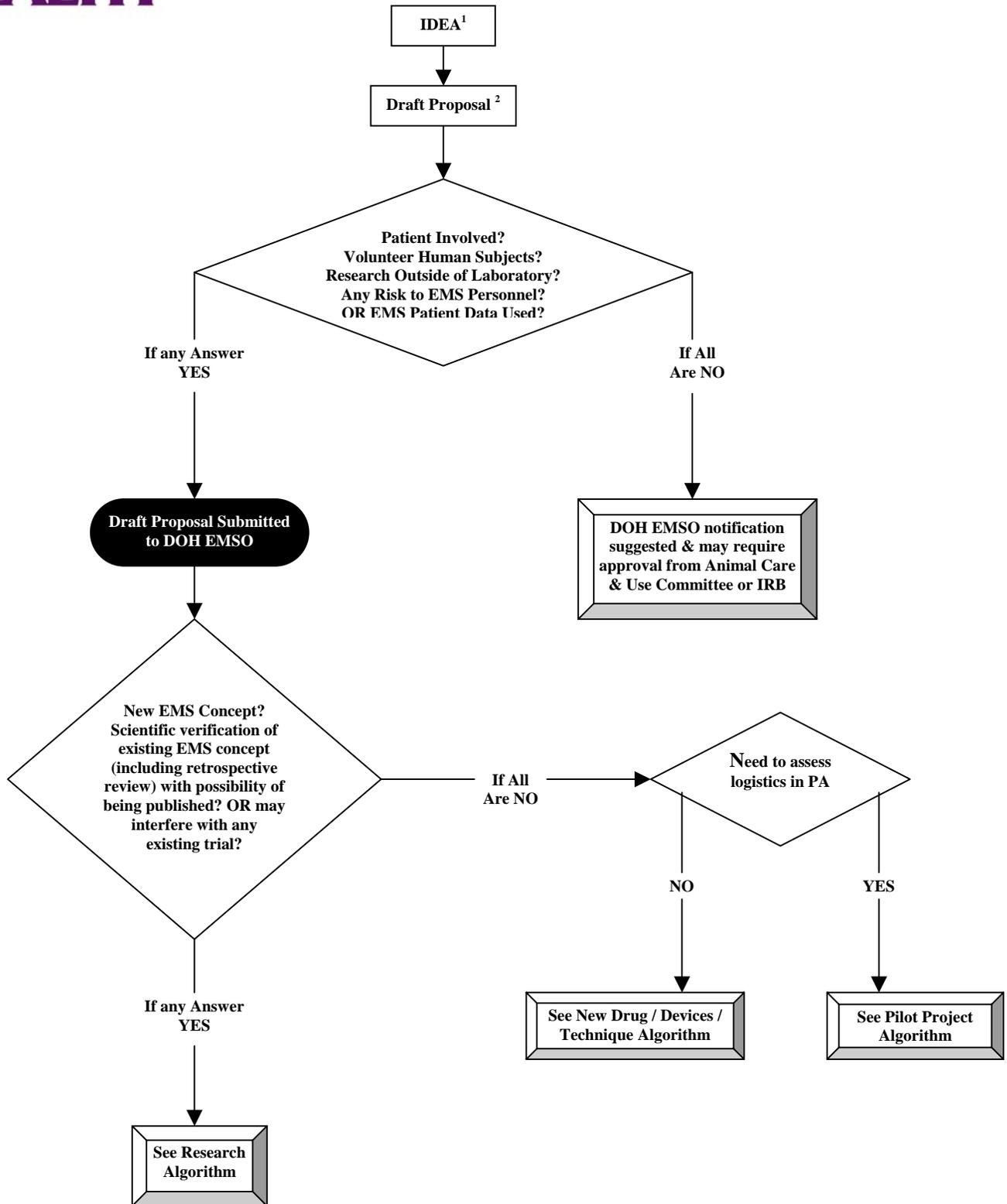




**EMS RESEARCH, PILOT PROJECTS,
OR EXPANSION OF SCOPE OF PRACTICE**

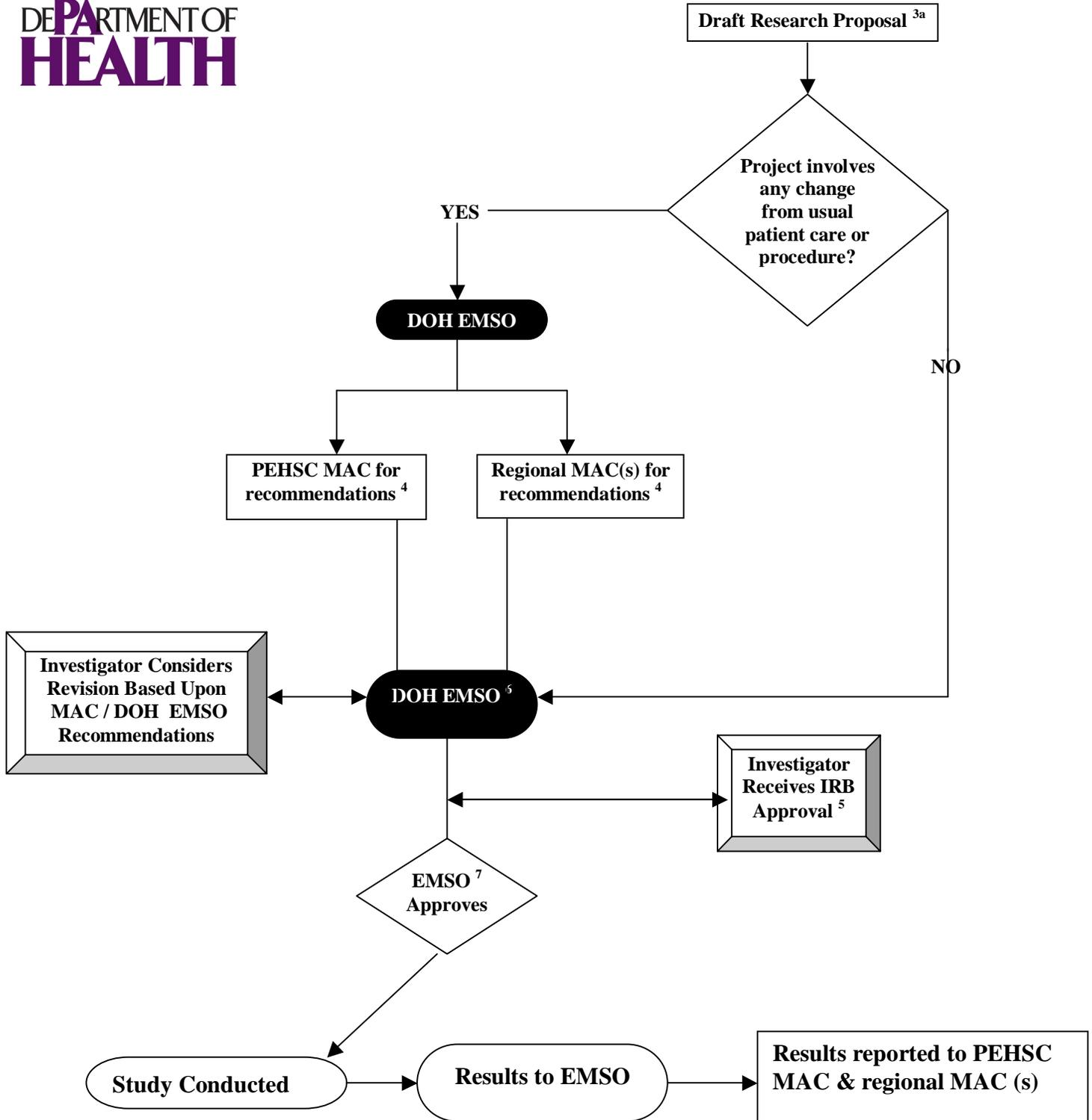


¹This idea can come from an individual, EMS service, EMS Region or related entity.

² Early contact with Regional Council(s) and Department of Health EMS Office is suggested.



RESEARCH ALGORITHM



^{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.

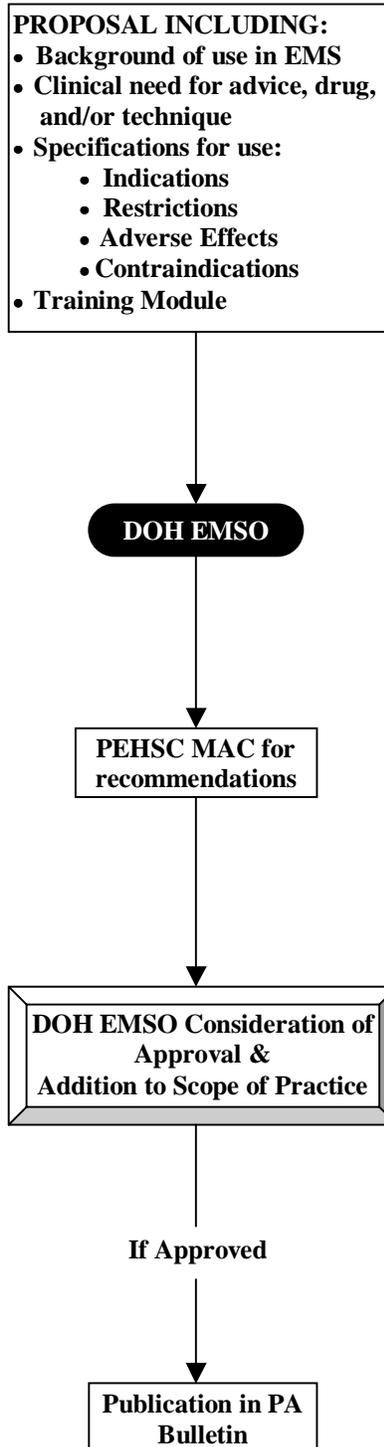
⁵ Approval from the investigator's IRB or PA state IRB is required before Department of Health EMS Office approves. The investigator may obtain IRB approval before or after MAC and DOH recommendations, but all revision must have IRB approval before DOH approval.

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.

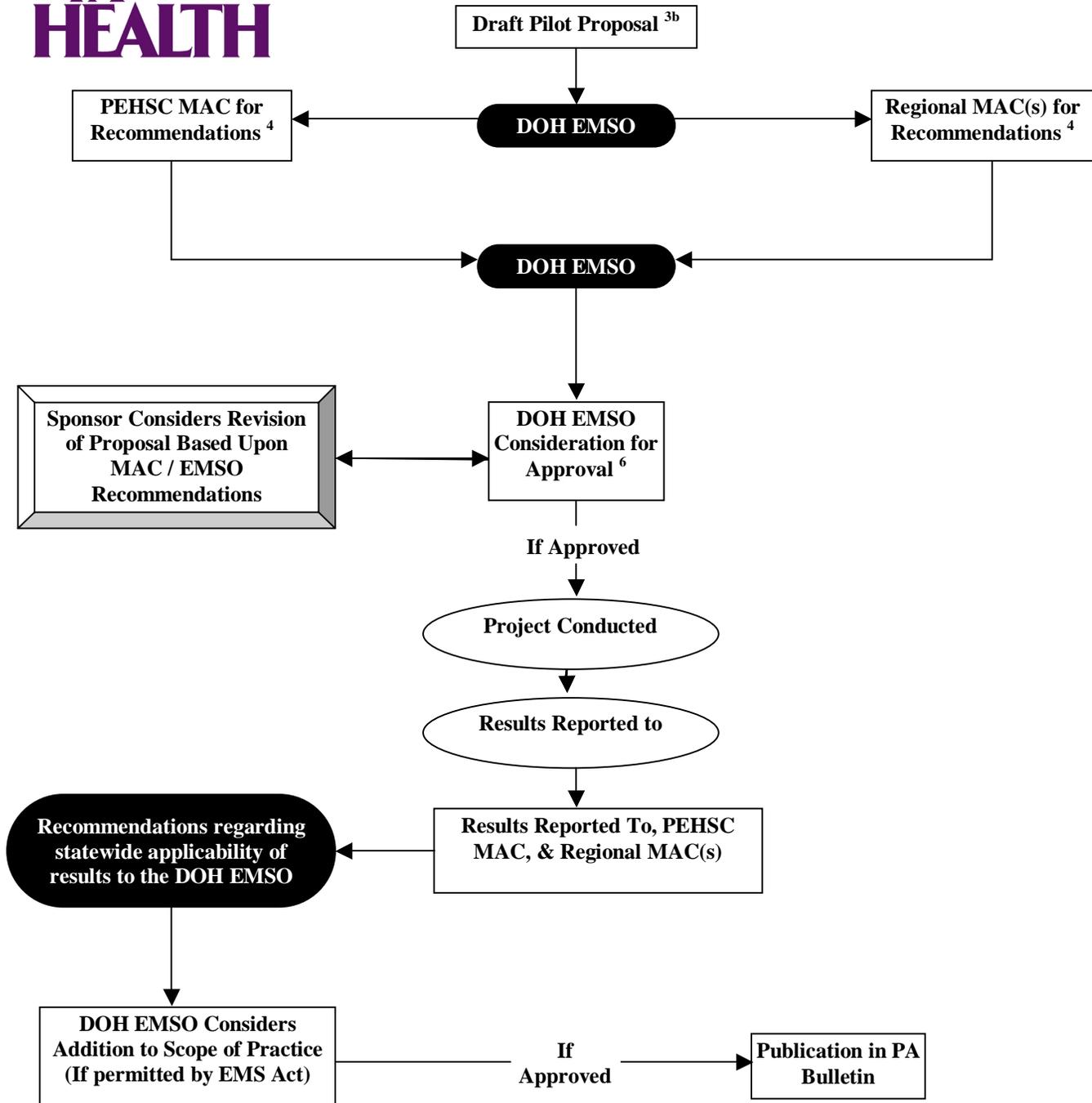


NEW DRUG / DEVICE / TECHNIQUE APPROVAL PROCESS





**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.