**OFFICE OF EMERGENCY MEDICAL SERVICES**Administrative Requirements ManualEFFECTIVE: 4/1/03 AUTHORIZATION: LG PAGE: 1 of 4A/R TITLE: WAIVERS FOR SPECIAL PROJECTS:  
APPLICATION PROCESS AND PROCEDURE FOR  
REVIEW AND APPROVALSUPERSEDES: 5/1/01**PURPOSE:**

To define the requirements for obtaining waivers for special projects, pursuant to 105 CMR 170.405.

**DEFINITION:**

105 CMR 170.405 provides that "at the discretion of the Department, regulations established in 105 CMR 170.000 may be waived for special projects which demonstrate innovative delivery of emergency medical care services. Proposals for special projects must be submitted to the Department in writing and no regulatory standards will be waived without explicit Department approval. Special projects will be considered experimental in nature and will be reviewed and renewed at such time periods as the Department shall establish." The Department interprets experimental to mean innovative, and would include in this category projects that would require institutional review board (IRB) review.

**APPLICATIONS:**

All applications for waivers for special projects must be submitted in writing to the Director of the Office of Emergency Medical Services (OEMS).

**A. Each application must include the following:**

1. Name and address of the Applicant
  - a. Licensed Ambulance Service(s) involved;
  - b. Regional affiliation(s)
  - c. Hospital(s) involved in project;
  - d. Contact person for special project, including address, phone number, FAX number and e-mail address.
  
2. A detailed description of the proposed special project, indicating why a waiver is required, including, but not limited to:
  - a. Level of EMT(s) involved in the special project;
  - b. The number of EMTs involved in the special project;
  - c. Name of Licensee;
  - d. Name of Medical Director(s) for service, project, and affiliate hospital, if relevant;
  - e. Regulation(s) requiring a waiver;
  - f. Purpose for/goals of special project;
  - g. Proposed time frame for special project;
  - h. Nature of the project;
  - i. Description of the population to be served by the special project;

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- j. A letter of review and evaluation from the relevant regional Medical Director and regional Executive Director;
  - k. A letter of review and evaluation from other relevant institutions involved in or impacted by the project, i.e., hospitals, MACEP, MMS, MHA, etc.
3. Analysis of available literature that supports the safety and efficacy of the proposed waiver and a description of why the public health and safety will not be compromised by the proposed special project.
  4. Documentation of out-of-hospital programs in other states with the same or comparable projects, including a description of the duration of the program and a summary of the results.
  5. Plan for QA/QI and on-going review of the special project with specific time frames, guidelines and evaluation tools. Include the name of the individual responsible for quality review and the organizational structure for quality review. This section should include a description of factors that would mandate that the special project waiver designation be withdrawn, if specific conditions are not met.

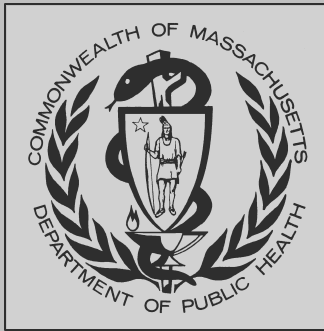
**B. Time Frames for Submission of Applications**

Applications may be submitted at any time to the Director of OEMS. Applications for special projects will be reviewed and voted on in a timely manner. The Director of OEMS will set the time schedule for review of such applications.

**C. Review of Applications for Special Projects**

OEMS staff shall review all applications for special projects upon receipt to determine whether the application is complete. No application will be considered if incomplete.

1. Two members of a volunteer group of emergency physicians and paramedics will be assigned to assist OEMS in the review of those clinically-based special project proposals that OEMS approves for further assessment. These individuals will review the project within 30 days and submit written comments, along with a non-binding recommendation, to OEMS. Prior to being assigned to review a particular special project proposal, volunteer group members must sign confidentiality and conflict of interest statements provided by

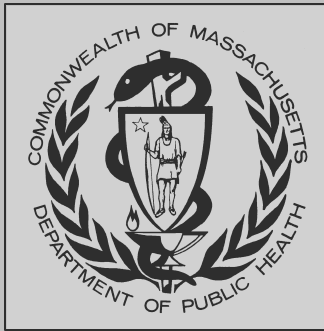
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OEMS. Volunteer group members shall not review a special project proposal that presents a conflict of interest, and shall abide by strict confidentiality requirements.

2. The Medical Services Committee will review all applications where clinical content is a component. The Committee, upon review, will make a non-binding recommendation on relevant clinical aspects of special project proposals.
3. The OEMS State Medical Director and Clinical Coordinator will review both the volunteer reviewers' recommendations and any Medical Services Committee recommendations, and make their own recommendations to the Director of OEMS. A committee to review special project waivers, as defined in subsection E, below, will be convened for each special project, when OEMS deems necessary.
4. The Department retains the final authority to oversee the review and approval or denial of the special project waiver. EMCAB committee review shall include clinical review by the Medical Services Committee described above and may include Executive Committee and other Standing Committee review, at the Department's discretion. Any approval shall be signed by the Commissioner or the Director of OEMS as designated and is the final decision of the Department regarding the special project waiver.

**D. Special Project Designation**

1. No special project shall commence until the applicant receives written authorization from the Director of OEMS or the Commissioner. The Department shall have the right to deny consideration of approval for any applicant who commences the special project prior to receiving explicit written approval from the Department.
2. The Department may attach conditions to the approval of special projects.
3. Special projects will be required to submit data results timely. Failure to submit data timely may disqualify the project from consideration for renewal or may constitute a basis for revocation of the approval.
4. Special projects may be approved for one or two years, and may be renewed for comparable periods, if the extension is justified to fulfill the stated goals of the project.



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5. Special projects once approved and underway may be amended only with the explicit approval of the Department.
6. The Department may deny, suspend or revoke any special project approval, under the following circumstances:
  - a. The continuation of the project is a threat to the public health and safety;
  - b. The project fails to adhere to all the terms and conditions of the special project designation;
  - c. The project fails to submit required data;
  - d. The project fails to cooperate with the Department.
7. The approval of a special project is within the discretion of the Department.
8. The denial of a special project is not subject to administrative appeal.

E. Committee to Review Special Project Waivers

1. The Department shall appoint as necessary a review committee charged with: (1) reviewing and analyzing the applications, (2) providing recommendations to the Department; and (3) conducting reviews of on-going projects.
2. Make up of the committee:
  - a. Individual with study design experience
  - b. Statistician
  - c. Representative from a School of Public Health
  - d. State Medical Director, OEMS
  - e. Deputy Director, Bureau of Health Quality Management
  - f. Legal Counsel
  - g. Prehospital provider representative
  - h. Appropriate medical discipline(s) – Hospital and/or Pre-hospital