Vermont Department of Health
Emergency Medical Services and Injury Prevention
Agency of Human Services

Application for Waiver of EMS Rules - Research

Name: _____

Phone: (H) _____ (W) _____

Mailing Address:_____

Town/City: _____ State: _____ ZIP Code: _____

E-mail Address_____

Name: _____

Phone: (H) _____ (W) _____

Mailing Address:_____

Town/City: _____ State: _____ ZIP Code: _____

E-mail Address_____

I/We hereby request the Vermont Department of Health waive EMS Rule(s) _____ from Vermont EMS Rules dated March 1, 2003 to carry out a research or demonstration project as described in this application. I/We understand a waiver must not reduce the quality of emergency medical care. I/We attest that the proposed project is in compliance with applicable statutes and the lawful rules of all involved agencies and the project medical director and other participants shall monitor and report the progress of the project on a schedule approved by the Department. Alteration of this document does not relieve me of any duty described in the Department-approved version of this form.

Title of Project: _____

I/We understand the Health Commissioner will hold a public hearing on this request unless I/we request otherwise, and all other parties agree.

☐ I **do** wish to waive a public hearing by the Health Commissioner.

☐ I **do not** wish to waive a public hearing by the Health Commissioner.

_____ _____
Signature of Applicant #1 Date

_____ _____
Signature of Applicant #2 Date

Description of Research or Demonstration Project

Title of Project:_____

Project Start Date:_____ Project End Date:_____

Project Medical Director:_____

On a separate sheet of paper, please provide the information requested below:

1) What information from this project will be provided to whom? What is the schedule for this reporting? Who is responsible for making these reports? *(Please attach copies of any data collection instruments that will be used in the project).*
2) Has this project been reviewed by an institutional review board (IRB)? *If so, please attach any correspondence from the IRB indicating their approval of the project.*
3) How will informed patient consent be obtained (if relevant) for this project?
4) Does the proposed project have other types of regulatory implications (e.g. OSHA, HIPAA, etc.)? If so please explain how compliance will be assured.
5) What are the financial arrangements for this project? Is there a budget? What is the source of funding and how will funds be expended? Will patients be charged for any portion of the costs for this research or demonstration?
6) What are the defined standards and controls for ensuring the safety of all patients and others who may be involved with the project? *Please attach any protocols, policies, or similar documents.* How would the persons involved in the research or demonstration project identify patients who might possibly be harmed? What process is there to halt the project or amend it if it is determined that patients or others are possibly being harmed?

Title of Project:_____

All agencies and districts included in this research or demonstration project must provide proof of support. If additional signature blocks are necessary, please make copies of this page and include them with the application.

HEAD OF SERVICE

I attest as head of _____, a Vermont licensed EMS agency, that this organization supports this waiver request.

_____ _____ _____
Signature Print Name Date

HEAD OF SERVICE

DISTRICT BOARD CHAIR

I attest as Chair of Vermont EMS District # _____ that this district's Board of Directors supports this waiver request.

_____ _____ _____
Signature Print Name Date

DISTRICT MEDICAL ADVISOR

I attest as District Medical Advisor for Vermont EMS District #_____ that I support this waiver request.

_____ _____ _____
Signature Print Name Date

VERMONT EMS APPROVAL

This application for a waiver of EMS Rules for the purpose of a research or demonstration project has ☐ has not ☐ been approved.

_____ _____
Signature, VTEMS Director Date

Section 12: Standards for Waiving EMS Rules

12.1 Waivers of rules for research and demonstration projects.

12.10 In the interest of promoting the growth of EMS technology and improving methods or techniques for the delivery of emergency medical treatment, the Department may waive provisions of these rules for research or demonstration purposes when:

12.101 The proposed project has definite start and ending dates.

12.102 There is a physician named as the project's medical director.

12.103 There is agreement of the medical facilitie(s), EMS District Board(s), ambulance and responder service(s), and other significant groups involved with the proposed project.

12.104 There are defined standards and controls for assuring the safety of all patients and other persons who may be involved with the proposed project.

12.105 The proposed project is in compliance with applicable statutes and the lawful rules of all other involved agencies.

12.11 All waiver arrangements described in Section 12.10 shall be in writing.

12.12 The project medical director and other participants shall monitor and report the progress of the project on a schedule approved by the Department.

12.13 The Department may revoke waivers awarded under this section at any time. Opportunity for a hearing with the Commissioner of Health shall be given within 10 days of the revocation. Decisions of the Commissioner may be appealed to the Board.

12.14 All applicants for waivers of these rules shall apply on forms available from the Department.