§ 8:41-5.1 Research proposals

(a) As utilized in this subchapter, the following terms are defined as follows:

1. "Research" means a scientific investigation designed to establish facts and to analyze their significance, including:
   
i. Any study directed at systemizing data related to the causes, mechanisms, diagnosis and treatment of injuries;
   
   ii. Data collection for purposes other than EMS management or evaluation; and
   
   iii. Any other utilization of EMS client data, unless specifically authorized by this chapter;

2. "Principal investigator" means the person responsible for proposing and coordinating the research project;

3. "Human subject" means the person under consideration who is affected with a disease or condition that is being treated or observed with medical and surgical procedures and about whom the researcher obtains:

   i. Historical data (for example, initial symptoms, circumstances surrounding the event, associated medical conditions) through intervention or interaction with the patient or their family; and

   ii. Identifiable private and/or confidential client data as recorded in any pre-hospital, acute care hospital and/or health care facility medical record;

4. "The Institutional Review Board (IRB)" means the board established by an acute care hospital to review biomedical and/or behavioral research using human subjects that is conducted at or supported by that hospital, in order to protect the rights of the human subject, and to approve said research; and

5. "Participating organizations" means volunteer, municipal or proprietary BLS ambulance services, mobile intensive care programs, specialty care transport services, air medical services...
and/or acute care hospitals.

(b) No provider shall engage in any prospective research activity involving drug trials or invasive procedures, unless first authorized to do so by the Commissioner.

(c) The procedure to request approval to conduct research projects shall be as follows:

1. The principal investigator shall first meet the requirements of all applicable Federal regulations including, but not limited to, those at 42 U.S.C. §§ 6a, III, G289;

2. The principal investigator shall obtain the approval of the IRB at the acute care hospital sponsoring or endorsing the study;

i. If the principal investigator is not a member of that sponsoring hospital's medical staff, the proposal shall include the name of the hospital's principal investigator responsible for the conduct of the study;

3. The principal investigator shall obtain approval of the provider's medical director. The medical director has ultimate authority and responsibility for the conduct of the research project;

4. The application shall also include specification of any procedure or drug that is proposed that is not manifestly approved by this chapter;

5. If the proposal is directed to operational systems and is not directly related to human subjects, the principal investigator shall submit documentation that IRB approval is not necessary;

6. Forty copies of the proposal shall be submitted to OEMS no later than 30 calendar days before the scheduled meeting of the MICU Advisory Council at which the principal investigator wishes to present the proposal;

7. The proposal shall be reviewed at the MICU Advisory Council meeting or by a research subcommittee as appointed by the chair of the MICU Advisory Council. The MICU Advisory Council or subcommittee shall review the proposal, make any comments it deems necessary, and make a recommendation with regard to approval or disapproval of the proposal. The recommendation, comments and proposal shall be forwarded to the Commissioner by OEMS; and

8. The Commissioner shall have final authority in the approval or disapproval of all research studies. The Department shall notify the principal investigator of its determination via mail. The study shall not be started until approval is obtained from the Commissioner.

(d) The format of the proposal shall include:

1. Background information, including rationale and relevant literature;

2. Specific aims and objectives, which shall be clearly stated, including the hypothesis and data to be gathered or tested;

3. Significance, relevance, benefits of and justification of the research;

4. Details of the methods utilized, including research design, how results shall be analyzed, number and type of clients, research tools utilized, amount of time necessary and any risks involved;

5. If patient procedures or drugs are needed, an explanation of the procedures, risks,
frequency, duration and precautions in detail, and a summary of the competence of personnel performing the procedure and the time frames of the study;

6. A detailed description of the mechanisms of patient protection, including:

i. How confidentiality of client data shall be maintained, including methods of safeguarding client-identifiable data; and

ii. If the research directly involves human subjects, how consent shall be obtained and documented; and

7. Administrative details, including budget, facilities utilized, and personnel issues.

(e) The Commissioner retains the right to revoke or suspend approval for any research project, regardless of stage of the research, for violations of the terms of the approval, violations of any part of this chapter or any applicable law, rule and/or regulation, violations of patient's rights or confidentiality or for reasons of patient safety.

(f) The principal investigator shall submit interim reports as required by the approval notice to the MICU Advisory Council. These reports shall include:

1. A brief summary of the project with the methodology of the study;

2. The objectives of the study;

3. The results of the study, to date;

4. The amount and type of work remaining; and

5. Any conclusions reached to date.

(g) The principal investigator shall submit a final report to the Commissioner, OEMS and the MICU Advisory Council, including a one page abstract.

(h) If the proposal involves a therapeutic agent not approved in accordance with N.J.A.C. 8:41-6.1, the Commissioner may authorize the utilization of said agent in his or her approval of the study. The Commissioner's approval shall specify the length of time the agent may be utilized, and shall be subject to the terms and conditions imposed in the approval notice. Thereafter, if the medication is to be continued, it must be added to N.J.A.C. 8:41-6.1 in accordance with the rulemaking provisions of the New Jersey Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and the Rules for Agency Rulemaking, N.J.A.C. 1:30. Only programs officially designated by the principal investigator and authorized by the Commissioner shall utilize any medication under study.