	Maryland Institute for Emergency Medical Services Systems		
	Policy: Human Subjects Research Policy		
	Originator: Attorneys General Office		
	Policy Number	Effective Date	Revision Date
	501.0	March 22, 2010	n/a

Purpose: By statute, the EMS Board shall "…periodically participate in or do analyses and studies that relate to emergency medical services." Education Article §13-508 (b)(3). Further, the MIEMSS Executive Director shall "…coordinate programs of research and education that relate to emergency medical services." Education Article §13-510(5). MIEMSS shall ensure compliance with applicable law and regulations governing human subjects research, as well as appropriate ethical safeguards, where such analyses, studies, or research programs: 1) involve human subjects and 2) are not exempt under 45 CFR 46.101 (b).

Definitions:

- Federalwide Assurance (FWA) - a written document submitted by an institution (not an Institutional Review Board) that is engaged in non-exempt human subjects research conducted or supported by HHS. Through the assurance, an institution commits to HHS that it will comply with the requirements set forth in the regulations for the protection of human subjects at 45 CFR part 46.

- Human Subjects Research - A systematic investigation performed with human subjects (including development, testing, and evaluation) designed to develop or contribute generalized knowledge, regardless of the source of funding.

- Institutional Review Board (IRB) - The group or committee that is given the responsibility by an institution to review that institution's research projects involving human subjects research. The primary purpose of the IRB review is to assure the protection of the safety, rights, and welfare of the human subjects.

- Data Access Committee (DAC) – A committee comprising members of MIEMSS staff tasked with: reviewing all requests to perform or participate in human subjects research to assure completion of necessary forms and compliance with requirements; determining appropriateness of the research; and submitting a recommendation to the Executive Director for approval or denial.

- Research Intervention – A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge which includes physical procedures by which data are gathered (e.g., venipuncture) or manipulations of the subject or the subject's environment performed for research purposes.

1. MIEMSS participation in human subjects research shall be limited to the following:

   A. In accordance with appropriate Institutional Review Board approval and with appropriate safeguards to maintain the confidentiality of medical data, human subjects research that involves data research only and does not require a research intervention may be approved by the Executive Director of MIEMSS; or

   B. In accordance with appropriate Institutional Review Board approval, appropriate safeguards to maintain the confidentiality of medical data, compliance with the requirements of COMAR Title 30 and subject to EMS Board approval, MIEMSS may promulgate research supplemental protocols to facilitate appropriate EMS field research involving human subjects.

2. To further insure that all human subjects research set forth in this policy complies with proper ethical safeguards, MIEMSS shall obtain and maintain a Federalwide Assurance (FWA) from the Office for Human Research Protections (OHRP) of the United States Department of Health and Human Services (HHS).

   A. The signatory official for executing the FWA shall be the MIEMSS Deputy Director.

   B. The Human Protections Administrator shall be the State Emergency Medical Services Medical Director and the MIEMSS Deputy Director.

3. Approval process for human subjects research:

   A. Submission to the DAC of a completed research application in a form acceptable to MIEMSS.

      a. Applications shall be accompanied by:

         i. a completed form indicating approval by an appropriate IRB; and

         ii. other documents as MIEMSS may require.

   B. Review of completed applications by DAC and recommendation for approval or disapproval.

C. Submission of the DAC recommendation to the Executive Director for approval or denial; and

D. For promulgation of research supplemental protocols, submission to the EMS Board and a MIEMSS approved IRB for approval.

Policy approved by MIEMSS:

Date: 3/23/10

Signature: _____

Robert R. Bass, MD
Executive Director