EASTERN VIRGINIA MEDICAL SCHOOL COMPLIANCE PLAN

I. <u>EVMS Mission Statement</u>

Eastern Virginia Medical School (EVMS) is an academic health center dedicated to achieving excellence and fostering the highest ethical standards in medical and health professions education, research, and patient care. Our vision is to improve the health of our communities and to be recognized as a national center of intellectual and clinical strength in medicine. Realizing this vision and fulfilling our mission requires the successful pursuit of four goals:

- 1. We will educate medical and health professions students who will be noted for their excellence in practice, human values, collegiality, and scientific curiosity and rigor.
- 2. We will enhance and strengthen our interdisciplinary research enterprise.
- 3. We will provide the highest quality, most effective health services by integrating the academic benefits of education and research into patient care.
- 4. We will strengthen and develop strategic partnerships to improve the health of our communities through education, research, and patient care.

II. EVMS Board of Visitors' Statement of Commitment to Compliance

The EVMS Board of Visitors is committed to the highest standards of ethical conduct and compliance with all applicable laws, regulations, and policies governing medical and health professions education, research, and patient care. The EVMS Compliance Plan demonstrates our organization's commitment to the compliance process. Everyone who works at EVMS is responsible for upholding this commitment and shall conduct all activities with the utmost ethical integrity, honesty and fairness and in compliance with all applicable laws, regulations, and policies.

III. Policy Statement

EVMS has established this Compliance Plan to ensure that quality medical education, patient care, and health care research occurs at this institution in a manner that fully complies with all applicable state and federal laws and regulations. It is the policy of EVMS, in voluntary compliance with Federal sentencing guidelines that:

1. All appropriate parties are educated about the applicable laws and trained in matters of compliance;

- 2. There is periodic auditing, monitoring and oversight of compliance with those laws:
- 3. There exists an atmosphere that encourages compliance and enables the reporting of non-compliance without fear of retribution;
- 4. Responsibility is not delegated to persons with a propensity to act in a non-compliance manner; and
- 5. Mechanisms exist to investigate, discipline and correct non-compliance.

This Plan provides for the existence of a Compliance Officer who has responsibility and accountability for EVMS compliance matters. However, each individual employee or agent of EVMS remains responsible and accountable for his or her own compliance with applicable laws. Confirmed acts of non-compliance will be subject to corrective action up to and including discipline. Discipline shall include all steps described in the Human Resources Policy and Procedure Manual and in the policies and regulations of the Employee Handbooks including, without limitation, termination and tenure revocation.

This Plan is intended to provide a framework for individual and departmental compliance efforts and to apply generally to all EVMS personnel and functions. Detailed plans, codes of conduct or manuals covering compliance in specific areas will be separately developed and will fit within this framework. Each individual compliance component must be submitted to and approved by the Compliance Officer.

IV. Compliance Officer

There shall be appointed an EVMS Compliance Officer. To avoid any issues related to a conflict of interest regarding legal or financial matters associated with compliance, the EVMS Compliance Officer has direct access to the President of EVMS, the Dean of EVMS, the Chair of the Audit and Compliance Committee of the EVMS Board of Visitors and the General Counsel of EVMS.

The EVMS Compliance Officer oversees the Compliance Plan, including the education of personnel regarding proper compliance, the auditing and monitoring of the status of compliance, and the reporting, investigation, discipline and correction of non-compliance. It is also his/her responsibility to ensure programs are in place to guarantee that significant discretionary authority is not delegated to persons with a demonstrated or suspected propensity for improper or unlawful conduct.

It is not expected that the EVMS Compliance Officer will have the knowledge or expertise necessary to ensure compliance with all laws and regulations or applicable standard operating procedures that affect the various departments of EVMS. He/she is responsible, however, for the overall program and must ensure that qualified, knowledgeable personnel within individual divisions or departments of EVMS assist in monitoring and educational functions.

The EVMS Compliance Officer reports on EVMS' fulfillment of its compliance goals to the EVMS Board of Visitors Audit and Compliance Committee at least quarterly and the EVMS Board of Visitors at least annually. The report includes but is not limited to: (1) the level of compliance or non-compliance found as a result of monitoring and auditing, (2) the success of efforts to improve compliance, including training and education (3) the non-delegation of discretionary authority to those with the propensity to act improperly, and (4) corrective or disciplinary action taken with respect to those found to be non-compliant. The EVMS Compliance Officer has full access to all personnel and relevant documentation (subject to state or federal confidentiality laws) deemed necessary to perform his/her oversight and reporting duties.

V. <u>Compliance Advisory Council</u>

There will be an EVMS Compliance Advisory Council charged with providing guidance to the EVMS Compliance Officer. The membership of the Compliance Advisory Council will include representatives and leaders from all appropriate EVMS departments including, but not limited to, human resources, office of research, research subject protection, environmental health services, graduate medical education, education, occupational health, finance, and information technology. The Compliance Advisory Council will also include members from risk management, administration, and others as appropriate.

The Compliance Advisory Council will provide guidance by:

- 1. Providing suggestions and information to assist in development of overall compliance program structure;
- 2. Reviewing program policies and procedures prior to submission for approval by the EVMS Board of Visitor's Compliance and Audit Committee;
- 3. Reviewing periodic status reports from Council members and the EVMS Compliance Officer;
- 4. Monitoring implementation of compliance program efforts by each department;
- 5. Reporting quarterly through the EVMS Compliance Officer to the EVMS Board of Visitors Audit and Compliance Committee regarding EVMS compliance activities and application of the Compliance Plan requirements;
- 6. Periodically reviewing and revising the EVMS Compliance Plan as required by changes to the law and/or procedures and policies of government;
- 7. Reviewing successful implementation of the education and training program that focuses on elements of the EVMS Compliance Plan so all appropriate personnel are knowledgeable of and comply with pertinent federal and state standards; and

8. Assisting in developing/reviewing programs and policies that encourage managers and other personnel to report suspected fraud and other improprieties without fear of retaliation.

VI. Reporting Compliance Issues

All personnel have the responsibility to comply with applicable laws and regulations and to report any acts of non-compliance.

Any employee who perceives or learns of an act of non-compliance should either: speak to his/her supervisor, call the EVMS Compliance Officer or use the EVMS Compliance Help Line. Compliance concerns may be reported verbally or in writing and may be anonymous. If an employee is unsure whether or not an issue is a compliance matter or has any questions about the existence, interpretation or application of any law, regulation, policy or standard, the issue or question should be directed, without hesitation, to the employee's supervisor, the EVMS Compliance Officer or through the Compliance Help Line.

Supervisors are required to report these issues through established channels in Human Resources and/or to the EVMS Compliance Officer. Reports to the Compliance Help Line may be made anonymously if the caller so desires, although giving a name and phone number generally makes investigating reports easier and more effective. Every effort will be made to preserve the confidentiality of reports of non-compliance. All personnel must understand, however, that circumstances may arise in which it is necessary or appropriate to disclose information. In such cases disclosures will be on a "need to know" basis only.

Anyone found to have known of acts of non-compliance and failed to report them will be subject to discipline.

No employee of EVMS shall in any way retaliate against another employee for reporting an act of non-compliance. Acts of retaliation should also be reported and will be investigated by the EVMS Compliance Officer or his/her designee. Any confirmed act of retaliation shall result in discipline.

All reports of non-compliance should be made in good faith and with the best of intentions. It will be considered a serious violation of EVMS policy for any person to intentionally make false accusations. Such an occurrence may result in disciplinary action up to and including termination of the accuser.

If a report of non-compliance involves human subject research or animal research, notice will be given to the appropriate EVMS oversight office, i.e. Office of Research Subject Protection, about the affected individual/investigator and/or studies.

VII. Investigation

All reports of potential violations of laws, regulations, policies or questionable conduct shall be logged by the EVMS Compliance Officer and an investigation will be authorized and initiated. The log will record the issue, the department or division affected and the resolution. This log will be treated as a confidential document and access will be limited to those persons at EVMS who have responsibility for compliance matters.

The EVMS Compliance Officer, or his/her designee(s), will investigate every report of non-compliance, however reported. Investigations will be done promptly and will consist of interviewing personnel, examining documents, and consulting with legal counsel, if necessary. All employees are expected to cooperate with those investigating such matters and non-cooperation may result in discipline.

The EVMS Compliance Officer or their designee(s) have full authority to interview any employee and review any document (subject to state and federal laws on confidentiality) he or she deems necessary to complete the investigation.

A written record of each investigation will be created and maintained by the EVMS Compliance Officer. He/she will make every effort to preserve the confidentiality of such records and will make any necessary disclosures on a "need to know" or legal basis only. Confidentiality, however, cannot be guaranteed.

A summary report of the findings of an investigation will be provided as appropriate to the complainant.

The EVMS Compliance Officer will report the results of each investigation considered significant to the EVMS Board of Visitor's Audit and Compliance Committee. The Compliance Officer shall recommend a course of discipline and/or other corrective action to be imposed. Periodically, the EVMS Compliance Officer will also provide a summary report of all investigations to the Audit and Compliance Committee of the EVMS Board of Visitors.

VIII. Corrective Action or Discipline

Every confirmed act of non-compliance may result in corrective action or discipline. In matters of non-compliance, corrective action or discipline will be according to applicable research and investigative policies and/or the findings of the appropriate regulatory agency or committee i.e. the Institutional Review Board or Animal Care and Use Committee, or others. Sanctions for severe or repeated instances of non-compliance may be recommended by the President and/or Dean of EVMS. Sanctions may include a requirement to follow a certain process or procedure in the future, restitution, and/or discipline.

A corrective action plan will be set forth in writing and should be designed to ensure that the issue of non-compliance is addressed and similar problems are prevented from reoccurring. A corrective action plan should include one or all of the following elements:

- 1. Identification of the specific areas requiring compliance improvement
- 2. Requirement of additional training
- 3. Change in policies or procedures
- 4. Further audit or investigation steps
- 5. Disciplinary action

IX. Education and Training

The EVMS Compliance Officer or his/her designee will monitor the education of personnel to ensure inclusion of program content which meets and abides by the specific laws and regulations affecting individual departments and personnel of EVMS. The EVMS Compliance Officer or members of the Compliance Advisory Council will inform personnel in their respective areas of changes in the laws or regulations through written communications and in-service training.

EVMS personnel are required to complete any compliance training assigned for their position in accordance with appropriate time frames and frequency.

All current and new EVMS personnel will have access to the Compliance Plan. Reference to its existence and how to secure a copy will appear in the EVMS Human Resources Policy and Procedure Manual and in the Employee Handbooks.

X. Monitoring and Auditing

The EVMS Compliance Officer will strive to ensure that the level of compliance in each division or department is audited periodically. He/she will arrange for external auditing as deemed necessary and appropriate in conjunction with the EVMS President and/or Dean. If the EVMS Compliance Officer discovers that a department's or individual's level of compliance is unacceptable, he/she may impose a plan of corrective action, which may include future monitoring of an individual or department on a more frequent basis. Corrective actions and sanctions for acts of non-compliance will be managed as outlined previously.

Any credible evidence of non-compliance believed by the EVMS Compliance Officer, or the EVMS Institutional Research Officer or other officials of EVMS, to violate criminal, civil, or administrative law will be reported by EVMS to the appropriate governmental authority.