

The East Carolina University Office of Institutional Integrity and School of Dental Medicine Compliance Program

I. STATEMENT OF PURPOSE

The East Carolina University Office of Institutional Integrity (OII) and School of Dental Medicine (SoDM) Compliance Program assists in fulfilling the vision of the SoDM to improve the health and quality of life by creating leaders with a passion to care for the underserved and leading the nation in community-based, service-learning oral health education. The Compliance Program enhances the mission of the SoDM by ensuring that its patient care activities, research, and operations are based on high professional and ethical business standards.

The Compliance Program further supports the mission of the SoDM to:

- Prepare leaders with outstanding clinical skills, an ethical bearing, sound judgment, and a passion to serve
- Provide educational opportunities for academically qualified individuals from historically underrepresented groups, disadvantaged backgrounds, and underserved areas
- Provide and enhance oral health services for underserved North Carolinians through implementation of community-oriented service learning and interprofessional collaborations
- Foster a learning environment where collaboration, creativity, diversity, and professionalism are embraced
- Influence future clinical practice and dental education through research, innovation, and discovery

The mission of the OII/SoDM Compliance Program is to assist in prevention, detection, and the rectification of non-adherence to applicable state and federal laws and regulations, and institutional policies and rules that may expose the SoDM to significant criminal or civil liability. These regulations include, but are not limited to, government and private payor reimbursement, the Federal Anti-Kickback Statute, the Prohibition on Physicians Self-Referrals (Stark Law), clinical research, and the confidentiality and integrity of patient information.

The Compliance Committee is responsible for overseeing the SoDM's Compliance Program. The duties of the Compliance Committee include:

- Compliance with applicable federal and state laws, rules, and regulations
- Compliance with the Code of Conduct for ECU Healthcare Services
- Compliance with the University and SoDM's policies and procedures
- Review and implement compliance initiatives as recommended by the Office of Institutional Integrity

The intent of the Compliance Program is to create a model that is designed to be an overall broad framework for compliance efforts of the SoDM. The Program is not intended to be, nor can it be, all-inclusive and therefore, the SoDM relies upon its internal personnel to meet the School's other and more specific compliance activities and challenges that are outside of the scope of this Compliance Program.

II. BASIC PRINCIPLES

Integrity: ECU and the SoDM honor integrity as a fundamental value and demonstrate the highest levels of professional conduct in all its dealings. Each individual associated with the School must perform his/her personal duties in accordance with these values.

Compliance with Legal Standards: The School follows all University policies, regulations, and rules and applicable federal and state laws and regulations. Each person associated with the School is charged with the responsibility to learn and understand the legal standards, which relate to his/ her duties, and to follow them accordingly.

III. COMPLIANCE OVERSIGHT AND STRUCTURE

A. Chief Integrity Officer

The Chief Integrity Officer (CIO) is responsible for the design, implementation, monitoring, and assessment of the SoDM compliance activities in relation to health care compliance. When necessary and appropriate, the CIO will also have direct contact with the Dean of the SoDM. In addition, assessments and/or reports may be provided to the Dean and Vice Dean.

The CIO will be the SoDM liaison with East Carolina University's Office for Research Integrity and Compliance for research related compliance.

Responsibilities of the CIO:

- Develop a comprehensive compliance program for SoDM;
- Identify regulatory compliance obligations of SoDM and its personnel.
- Provide guidance and assistance, in consultation with, Office of University Counsel, and other University offices;
- Develop and/or oversee the implementation of health care compliance educational training efforts and programs;
- Develop effective lines of communication throughout SoDM to enhance effectiveness of the Compliance Program;
- Coordinate investigations involving potential or alleged billing noncompliance, including HIPAA privacy and security, involving SoDM personnel;
- Monitor various operations of the SoDM to identify and resolve barriers to compliance.
- Recommend corrective action and /or appropriate discipline related to incidents of non-compliance;
- Assist, as appropriate, in the review of new SoDM policies and amendments of current standard operating procedures to maintain conformity and compliance with new regulatory developments;
- Interact with outside organizations and government offices, as necessary, to clarify regulatory requirements.

B. Role of the Compliance Committee

The Compliance Committee is responsible for overseeing the Compliance Program. OII, in conjunction with the Dean of the SoDM appoint members of the Compliance Committee.

Responsibilities of the Compliance Committee:

- Conduct annual review and analysis of the effectiveness of the OII/SoDM Compliance Program;
- Complete and recommend Program improvement;
- Preliminarily approve compliance-related standard operating procedures for submission to the Dean or Dean's Executive Council for final approval;
- Recommend and review risk assessments to determine priorities for the Chief Integrity Officer;
- Review compliance initiatives as recommended by the CIO and the Office of Institutional Integrity

If a voting member is no longer able to serve on the Committee, OII will work with the Dean to appoint a replacement.

Members with a one-year term are selected from the following:

- Office of Dental Education and Informatics
- Office of Business and Financial Affairs
- Office of Clinical Affairs
- Office of Extramural Clinical Programs
- Advance Education in General Dentistry (AEGD) Residency Program
- Chair, Pediatric Dentistry, Ortho. and Dentofacial Orthopedics
- Hospital Dentistry - General Practice Residency (GPR) Program
- Clinical Faculty Member
- CSLC Director
- Office of Research Innovation and Discovery
- Associate Dean, Student Affairs

Members with no term limits include:

- Executive Director of Business and Financial Affairs, SODM
- Chief Integrity Officer
- Director, Office of Institutional Integrity
- Compliance Specialist, SoDM

Ex Officio Members with voting rights include:

- Vice Dean, SoDM

Additional resources for the Compliance Committee that can be invited to attend as needed include:

- Representative from University Attorney's Office
- Representative from Enterprise Risk Management
- Representative from Office of Internal Audit and Management Advisory Services
- Representative from Office for Research Integrity Compliance
- Representative from Office of the Registrar

The Director, Office of Institutional Integrity will serve as the Chair of the Committee. Meetings will be held as deemed necessary by the Committee, but no less than annually. A summary of items addressed, and actions taken at each meeting will be recorded and retained by the Office of Institutional Integrity. Periodic reports will be shared with the Dean's Executive Council and other University officials, when necessary.

IV. STANDARDS OF CONDUCT

As part of the Compliance Program, the SoDM will establish and monitor adherence to the SoDM's guiding principles. The School's business will be conducted with integrity and in accordance with the principles contained in the Code of Conduct for ECU Healthcare Services. Adherence to these principles is essential to the mission of the School. It is the expectation that SoDM personnel will comply with all applicable laws, rules and regulations and will report violations to appropriate persons.

In addition, every new employee will be required to read the Code of Conduct for ECU Healthcare Services and sign an attestation annually.

The following Standards of Conduct are based upon general ethical and legal obligations.

A. Patient Care

All SoDM patients will be treated with respect and dignity. Each health care professional of the School will only provide health care services or items to patients within the scope of his/her license. Patients (or their legal representative) are entitled to a full understanding of their individual medical needs.

B. Ethical and Legal Responsibilities

The SoDM is committed to ensuring that it operates under the highest ethical standards. The business activities must comply with applicable laws and the absence of deception or fraud. No person will make, file, or use any false or fraudulent statements or documents in connection with the delivery of, or payment for, health care services or items.

C. Proper Coding and Billing Practices

Health care services must be accurately coded and timely billed according to payer requirements. Billing claims and patient records are expected to be accurate, complete, and detailed to the extent required by law and SoDM guidance. Dental services and items must be supported by adequate documentation in the patient's medical record.

D. Confidentiality

SoDM business information, patient health records, and student academic records will be treated in a confidential manner. Disclosure of patient information and/or business information will adhere to the School's procedures, University policy, and applicable laws.

E. Conflicts of Interest

Business activities will be conducted to avoid any conflict or interest of the appearance of a conflict of interest. SoDM employees are to avoid engaging in any activity or practice that violates University policies, state, or federal laws. In addition, employees will not participate in any activity that will jeopardize the SoDM.

F. Proper Referrals

Referrals are based upon the patient's health care needs and are made and accepted in accordance with the law. All proposed contractual relationships involving the SoDM are reviewed and approved by the Office of University Counsel prior to execution to ensure compliance with both the Anti-kickback Statute and Stark Law.

G. Internal and External Investigations and Accrediting Bodies

The SoDM will cooperate with all accrediting bodies (including SACS and CODA), internal investigations, and all legitimate government investigations.

H. Personnel Screening and Evaluation

All new employees undergo a criminal background check, which includes a search of applicable government sanction/exclusion lists, including the Office of Inspector General, U.S. Department of Health & Human Services' exclusions database. Additional lists and/or screenings may occur, as appropriate or required by law.

I. Safety Requirements

The SoDM will comply with various regulatory safety requirements that may include research, clinical, facilities, and others as required by law.

V. EDUCATION AND TRAINING

The SoDM is committed to providing education and training that will ensure compliance and that emphasize the School's commitment to legal and ethical conduct. Education is an integral part of an effective compliance program.

Training may be determined by the Chief Integrity Officer, in consultation with the Vice Dean, Dean, or other personnel as necessary. Training attendance will be documented. Any other department or office will be responsible for maintaining records of attendance for compliance training that may be conducted by other parties and may be asked by the Compliance Office to provide copies of these records. The Chief Integrity Officer will notify an employee's department Chair or supervisor in the event of failure to attend mandatory training. In some instances, the Chief Integrity Officer may make a recommendation regarding corrective and/or disciplinary action, depending on the severity of the circumstances.

VI. MONITORING

The SoDM prevents non-adherence to guidelines that may expose the School to significant criminal or civil liability. The CIO will collaborate with other campus leadership and assure that processes are in place to meet the regulatory requirements that govern the delivery of services provided by the SoDM.

The CIO will provide a mechanism for tracking and monitoring noncompliance and/or criminal conduct designed to achieve compliance with ECU policies and procedures, federal and state laws and regulations, and other guidance.

The Compliance Committee will annually review a comprehensive monitoring work plan that focuses on identified areas of risk, industry literature, the OIG work plan, or other identified sources.

Ad Hoc Monitoring

The Chief Integrity Officer will perform monitoring of any other areas as identified by the SoDM Dean or CIO. Areas for additional monitoring may be identified based on the OIG Work Plan or Advisory Opinions, any recent regulatory enforcement initiatives or settlements, Compliance Hotline calls/emails inquiries, or other risk areas identified at SoDM. Ad-hoc monitoring will be performed in consultation with the Office of University Counsel, Office of Internal Audit and Management Advisory Services and/or the CIO as necessary.

Results of audit/monitoring reports and developed management plans that monitor the mitigation of systematic issues of identified risk will be shared with OII/SoDM Compliance Committee, SoDM Dean, and appropriate SoDM and University personnel (e.g., Chief Integrity Officer, Office of University Counsel and Office of Internal Audit for ECU), as necessary.

VII. ENFORCEMENT AND PREVENTION

The SoDM and the University reserve the right to take disciplinary action or cause disciplinary action to occur against anyone who fails to comply with elements of the Compliance Plan. The Chief Integrity Officer, in collaboration with other University officials, will evaluate violations of compliance and refer cases as necessary for potential disciplinary action in accordance with University policy or other governing standards.

VIII. ORGANIZATION RESPONSE AND CORRECTIVE ACTION

The SoDM will respond consistently and decisively to detected deficiencies. As deficiencies are discovered through audits, reporting mechanisms, and other activities involved with the operation of the Compliance Program, corrective measures and disciplinary actions will be developed to address the noncompliance. Corrective action plans and other remedial actions will typically include, among other actions, personnel education and training, additional monitoring, and auditing, and can involve reporting to outside agencies as required.

IX. REPORTING CONCERNS

The SoDM recognizes that an open line of communication between the Chief Integrity Officer and personnel is essential to the success of the Compliance Program. Staff, faculty, residents, and students are strongly encouraged to report incidents of potential noncompliance with SoDM and University policies, regulations, and rules and applicable federal and state laws and regulations, or to seek clarification regarding legal or ethical concerns directly to their immediate supervisor, the Chief Integrity Officer, or via the OII or SoDM Compliance various hotline and email addresses. Non-employees may contact the individual with whom they traditionally interact with at the SoDM, the Chief Integrity Officer, or via the OII of SoDM Compliance hotlines or the compliance email addresses.

A summary, maintained by OII, of each anonymous or confidential report will be documented. When the SoDM receives such reports, the School will have a process in place to report incidents to the CIO. The CIO will work with the Department of Internal Audit for the University, or to the Office of University Attorney, as appropriate.

There will be no reprisals for inquiries or good faith reporting of actual or suspected violations of the Program or the Code of Conduct for ECU Healthcare Services. The OII and the SoDM will protect, to the fullest extent allowed by law, the identity of anyone reporting a violation. All reports will be fully investigated with protection of the identity of the subject(s) of the investigation as much as possible. It is also against University policy to retaliate or attempt to retaliate against anyone who makes a good faith report of a suspected or known violation.

Contact Information:

OII Compliance Hotline: 1-866-515-4587

OII Compliance Email: INTEGRITYCOMPLIANCE@ECU.EDU

SoDM Compliance Hotline: (855) 737-1846 or (252) 737-7234

SoDM Compliance Email: SODMCOMPLIANCE@ECU.EDU

Office of University Counsel: (252) 744-3013

Office of Internal Audit and Management Advisory Services: (252) 328-9025



D. Gregory Chadwick, DDS, MS

Date

Dean

East Carolina University

School of Dental Medicine