The East Carolina University School of Dental Medicine Compliance Program

I. COMPLIANCE MISSION and STATEMENT OF PURPOSE

The primary mission of the Compliance Office at East Carolina University School of Dental Medicine (SoDM) is to assist in fulfilling the vision of the SoDM by improving the health and quality of life of all North Carolinians by creating leaders with a passion to care for the underserved and by leading the nation in community-based, service learning oral health education. The Compliance Office 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 Compliance Office 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 mission of the SoDM Compliance Program is to assist in prevention, detection, and the rectification of non-adherence to guidelines that may expose the SoDM to significant criminal or civil liability.

The SoDM has established a Compliance Committee, which has the responsibility for overseeing the SoDM’s Compliance Program with respect to: compliance with federal and state laws, rules and regulations applicable to SoDM’s business; compliance with the SoDM’s codes of conduct; compliance with the University and SoDM’s policies and procedures; and compliance with applicable clinical accreditation standards.

The intent of the Compliance Program is to create a model that is designed to be an overall 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 personnel’s sense of fairness and integrity to meet the School’s various challenges.

II. BASIC PRINCIPLES

Integrity: The School honors integrity as a fundamental value and demonstrates 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. Compliance Officer

The Compliance Officer (CO) is responsible for the design, implementation, monitoring, and assessment of the SoDM compliance activities in relation to health care compliance. The CO has a dual reporting relationship to the Vice Dean of the SoDM and the Chief Institutional Integrity Officer (CIIO), Health Sciences Division at East Carolina University. When necessary and appropriate, the CO will also have direct contact with the Dean of the SoDM. In addition, assessments and/or reports may be provided to the Dean, Vice Dean, or CIIO.

The CO will be the SoDM liaison with East Carolina University Office of the Registrar for educational compliance and with East Carolina University Office for Research Integrity and Compliance for research related compliance.

Responsibilities of the Compliance Officer:

- Develop a comprehensive compliance program for SoDM;
- Identify and provide support regarding regulatory compliance obligations of SoDM and its personnel;
- Provide guidance and assistance in consultation, with the Division of Health Sciences, Office of Institutional Integrity, 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 noncompliance, including HIPAA privacy, 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 noncompliance;
- Assist, as appropriate, in the review of new 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. The Dean of the SoDM appoints members of the Compliance Committee.

Responsibilities of the Compliance Committee:

- Conduct annual review and analysis of the effectiveness of the 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 Compliance Officer;
• Review compliance initiatives as recommended by the Compliance Officer; and
• Consult with the Institutional Integrity Office to ensure coordination with Health Sciences and ECU.

Compliance Committee members serve for a one-year term. Members may be appointed for one additional consecutive term. If a voting member is unable to complete a term on the Committee, the Dean will appoint a replacement. The replacement will serve the remaining portion of the term and may then be appointed for up to one subsequent consecutive term.

Members are selected from the following areas:

• 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
• Hospital Dentistry – General Practice Residency (GPR) Program
• Clinical Faculty Member: Rotating member appointed for one year term
• Office Of Institutional Integrity, Division of Health Sciences
• Office of Research Innovation and Discovery

Members with no term limits include:

• Executive Director of Business and Financial Affairs
• Compliance Officer

Ex Officio Members with voting rights include:

• Vice Dean, SoDM
• Chief Institutional Integrity Officer, Division of Health Sciences

Additional resources for the Compliance Committee 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 SoDM Compliance Officer and Healthcare Regulatory Specialist, Office of Institutional Integrity, will serve as Co-Chairs of the Committee. Meetings will be held as deemed necessary by the Committee, but no less than quarterly. A summary of items addressed and actions taken
at each meeting will be recorded and retained by the Compliance Officer. 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. More specifically, the SoDM codes of conduct designed to promote ethical conduct and outline fundamental principles for compliance within the School. The School’s business will be conducted with integrity and in accordance with the principles contained in the codes of conduct. 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. All new employees will also be provided a copy of the SoDM Compliance Program document and the SoDM Code of Conduct. In addition, every new employee will be required to read the SoDM Code of Conduct 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 Compliance 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 Compliance Officer will notify an employee’s department Chair or supervisor in the event of failure to attend mandatory training. In some instances, the Compliance 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 Compliance Officer 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 Compliance Officer 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.

A. Ad Hoc Monitoring
The Compliance Officer will perform monitoring of any other areas as identified by the SoDM Dean or Chief Institutional Integrity Officer, Health Sciences. 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 Health Sciences Chief Institutional Integrity Officer 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 SoDM Compliance Committee, SoDM Dean, and appropriate SoDM and University personnel (e.g., Health Sciences Chief Institutional 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 SoDM Compliance 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 Compliance 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 Compliance Officer, or via the SoDM Compliance hotline or the compliance email address. Non-employees may contact the individual with whom they traditionally interact with at the SoDM, the Compliance Officer, or via the SoDM Compliance hotline or the compliance email address.

A summary, maintained by the Compliance Office, of each anonymous or confidential report will be documented. The SoDM Compliance Officer will have a process in place to identify the infractions and determine what level to report incidents to the CIO of Health Sciences, 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 SoDM codes of conduct. The SoDM will protect, to the fullest extent allowed by law, the identity of anyone reporting a violation. All reports will be investigated with protection of the identity of the subject(s) of the investigation to the fullest extent possible.
It is a serious violation of the SoDM policy to falsely report a Code of Conduct violation or to retaliate or attempt to retaliate against anyone who makes a good faith report of a suspected or known violation.

Contact Information:
SoDM Compliance Hotline: (855) 737-1846 or (252) 737-7234
SoDM Compliance Email: SODMCOMPLIANCE@ECU.EDU
Division of Health Sciences, Office of Institutional Integrity Hotline (866) 515-4587
Office of University Counsel: (252) 744-3013
Office of Internal Audit and Management Advisory Services: (252) 328-9025

\[Signature\]
D. Gregory Chadwick, DDS, MS
 Dean
East Carolina University
School of Dental Medicine

\[Signature\]
Date
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