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STANDARD OPERATING PROCEDURES

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# ACRONYMS

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>CATTS</td>
<td>Computerized Annual Training and Tracking System</td>
</tr>
<tr>
<td>COI</td>
<td>Conflict of Interest</td>
</tr>
<tr>
<td>EPLS</td>
<td>Excluded Parties List System</td>
</tr>
<tr>
<td>GSA</td>
<td>General Services Administration</td>
</tr>
<tr>
<td>HIPAA</td>
<td>Health Insurance Portability and Accountability Act</td>
</tr>
<tr>
<td>MCA</td>
<td>Medicare Coverage Analysis</td>
</tr>
<tr>
<td>MUHA</td>
<td>Medical University Hospital Authority (MedCenter)</td>
</tr>
<tr>
<td>MUSC</td>
<td>Medical University of South Carolina</td>
</tr>
<tr>
<td>OIG</td>
<td>Office of Inspector General</td>
</tr>
<tr>
<td>OSHA</td>
<td>Occupational Safety and Health Administration</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
</tr>
<tr>
<td>UCO</td>
<td>University Compliance Office</td>
</tr>
<tr>
<td>UMA</td>
<td>University Medical Associates</td>
</tr>
</tbody>
</table>
UNIVERSITY COMPLIANCE OFFICE QUALITY MANUAL

1.0 PURPOSE AND SCOPE

1.1 Purpose

The Medical University of South Carolina (MUSC) supports an interprofessional environment for learning and discovery through education of health care professionals and biomedical scientists, research in the health sciences and provision of comprehensive health care through various programs that promote integrity by complying with regulations and/or policies. This document sets forth the basic criteria to ensure compliance with regulations and/or policies.

1.2 Scope

This document specifies the general requirements for the implementation of a quality system for the MUSC University Compliance Office (UCO).

2.0 RESPONSIBILITIES

2.1 The University Compliance Program provides a proactive program to ensure full compliance with all applicable policies, procedures, laws and regulations. The Director, UCO responsibilities include development, implementation and management of a program of action designed to promote ethical behavior in accordance with MUSC’s core values as expressed in the Mission Statement and Code of Conduct.

2.2 The UCO serves as a focal point for an understanding of MUSC’s total compliance responsibilities. The UCO proactively seeks to train faculty, staff, and students to provide for the active solicitation and discovery of concerns followed by an appropriate investigation into problem areas and the timely resolution of issues.

3.0 REQUIREMENTS

3.1 This Quality Manual shall be managed by the Director, UCO and approved as required by Standard Operating Procedure (SOP) 01, Control of Quality System Documentation.

3.2 The Director, UCO shall ensure all quality system documentation is prepared and maintained as required by SOP 01, Control of Quality System Documentation.

3.3 The performance of internal audits will be documented.

3.4 The Director, USO shall schedule a quality system review at least annually as required by SOP 03, Quality System Review. The conduct of this review shall be documented.
4.0 RESOURCES TO SUPPORT THE QUALITY SYSTEM

4.1 Resource planning for staffing, travel, and training shall be conducted annually to determine the support requirements for the Quality System.

4.2 Expenditures are evaluated and estimated for adequate resources required for managing the Quality System.

5.0 EVALUATION OF THE QUALITY SYSTEM

5.1 The Quality System is evaluated and monitored through internal audits and investigations into allegations.

5.2 The Director, UCO or designated representative conducts the internal audit.

5.3 The Director, UCO or designated representative conducts investigations into allegations.

6.0 DOCUMENTATION OF THE QUALITY SYSTEM

6.1 The quality system requires documentation of actions performed. These documents must be regularly updated to reflect changes in requirements and responsibilities. Changes will be made as required by SOP 01, Control of Quality System Documentation.

7.0 THE QUALITY SYSTEM PROCESS

7.1 The Quality System can be divided into three sections: described, documented, and demonstrated. This Quality Manual defines the quality objectives and polices describing the Quality System. Standard Operating Procedures (SOPs) translate the Quality Manual into documented instructions of how the Quality System is implemented. Records demonstrate the implementation of the SOPs and effective operation of the Quality System.

8.0 TRAINING AND QUALIFICATION

8.1 The Director, UCO shall have sufficient managerial, communication, and interpersonal skills to plan, implement, and assess the Quality System.

8.2 Auditors shall have education, experience, and training to conduct internal audits and shall remain independent of the audited area. The auditor has the authority to document deficient conditions.
9.0 DOCUMENTS AND RECORDS

9.1 Quality records document the performance of the Quality System. These records will be maintained as required by SOP 01, Control of Quality System Documentation. Some of these documents and records include internal audit reports, SOPs, forms, and protocols. It is necessary for these documents and records to be retained.

10.0 IMPLEMENTATION OF THE QUALITY SYSTEM

10.1 The Quality System is implemented through the use of SOPs.

10.2 The requirements for preparing, approving, and issuing of SOPs are specified in SOP 01; Control of Quality System Documentation.

10.3 The requirements for the annual review (evaluation) of the Quality System are specified in SOP 02; Quality System Reviews.

10.4 The requirements for the performance of internal audits are specified in SOP 03; Internal Audits.

10.5 The requirements for an investigation procedure are specified in SOP 04; Investigation Procedure.

10.6 The requirements for screening faculty & staff, vendors and contractors are specified in SOP 05; Excluded Parties Screening.

10.7 The requirements for the conduct of compliance training are specified in SOP 06; Compliance Training.

10.8 The requirements for the investigation of suspected identity theft are specified in SOP 07; Investigation of Suspected Identity Theft.

11.0 QUALITY IMPROVEMENT

11.1 The individual elements of a Quality System must blend to form a system that is easily adaptive to change. Quality improvement can only be accomplished by the implementation of changes. The individual elements of the Quality System include the performance of internal audits, ensuring implementation of corrective action, conduct of annual reviews, and finally, communication of the Quality System’s performance.
SOP 01
CONTROL OF QUALITY SYSTEM DOCUMENTATION

1.0 PURPOSE AND SCOPE

1.1 Purpose and Scope

This SOP specifies the requirements for the control of Quality System documentation. This SOP specifies the requirements for the preparation, approval, and maintenance of Quality System documents. These documents are this manual (including SOPs), documentation of internal audits, and associated forms.

2.0 REQUIREMENTS

2.1 The Director, UCO shall manage this manual (including SOPs).

2.2 The Director, UCO shall prepare, assure the proper approval, issue, and maintain all Quality System documentation.

2.3 The format of each SOP shall be similar to the format of this SOP.

2.4 For the first issue of this manual, the revision and change number shall be zero. Each revision and change shall follow a sequential number, as applicable.

2.5 Other SOPs shall be prepared as determined.

2.6 When an activity described in this manual (including SOPs) takes a significantly different direction, this manual shall be revised/changed, as required.

2.7 This manual (including SOPs), documentation of internal audits, and associated forms shall be reviewed annually and revised/changed, as required. The Director, UCO shall conduct this review at the same time as the annual review of the Quality System. The conduct of this review shall be documented.

2.8 Revisions/changes to this Quality Manual shall be approved by the Director, UCO.
SOP 02
QUALITY SYSTEM REVIEWS

1.0 PURPOSE AND SCOPE

1.1 Purpose and Scope

This SOP specifies the requirements for the annual review and for considering alternatives to improve the effectiveness of the Quality System.

2.0 REQUIREMENTS

2.1 The Director, UCO will schedule a review of the performance of the Quality System at least annually.

2.2 The accomplishment of this annual review shall be documented. The Director, UCO will report the results of this annual review to the Vice President for Academic Affairs and Provost.

3.0 PERFORMANCE OF THE ANNUAL REVIEW

3.1 The Director, UCO shall initiate the annual review during the first quarter of the calendar year.

3.3 The agenda for this annual review shall include:


2) Review of this manual (including SOPs) to identify and remove obsolete requirements.

3) Evaluation of proposed changes to the Quality System.
1.0 PURPOSE AND SCOPE

1.1 Purpose and Scope

This SOP specifies the requirements for the conduct of internal audits.

2.0 REQUIREMENTS

2.1 The Director, UCO and/or designated representative shall conduct the internal audit.

2.2 The Director, UCO shall prepare and maintain an annual internal audit schedule based on the status and importance of activities covered by the Quality System.

3.0 PRE-AUDIT PREPARATION

3.1 The auditor will notify the department head [or Principal Investigator (PI) for research studies] and schedule a time and place to conduct the audit.

4.0 THE AUDIT PROCESS

4.1 The auditor shall initiate and complete an audit checklist to document the proper performance of the audit. The audit will consist of a review of documentation to confirm conformance to requirements.

4.2 The auditor shall compare study documentation against the requirements of this Quality Manual (including SOPs), appropriate regulations, guidelines, the protocol, policies, etc.

4.3 The auditor will have access to files and records to verify conformance.

4.4 An audit finding is defined as a finding violating appropriate regulations, guidelines, the protocol, SOPs and/or policies.

4.5 The auditor will hold an exit briefing with the department head, PI and/or study coordinator. The purpose of this briefing is to discuss each audit finding.

4.6 Results of the audit will be documented.

4.7 A copy of all audit reports and correspondences documenting the implementation and/or resolution of audit findings will be retained.
SOP 04
INVESTIGATION PROCEDURE

1.0 Introduction
1.1 The Director, UCO or designated representative will thoroughly investigate and provide resolution of any allegation or provide an answer to any question formally presented.

1.2 This procedure applies to allegations or questions from faculty, staff, contractors, students, volunteers or from members of the general public.

2.0 Definitions
2.1 Confidential Hotline – A 1-800 toll free number for reporting allegations. The hotline is staffed by an outside vendor who reports inquiries to the MUSC Compliance Office(s).

3.0 Reporting Mechanisms
3.1 Allegations are generally reported (but not limited) to the Compliance Office by one of the following:
   1) Confidential Hotline;
   2) Telephone;
   3) E-Mail;
   4) Fax;
   5) Mail (campus or US Postal Service);
   6) Walk-in (face to face, etc.); and
   7) Identified during the conduct of an audit.

4.0 Anonymity
4.1 All precautions will be taken to ensure the anonymity of anyone reporting an allegation. Individuals have the right to remain anonymous, as allowed by law. Individuals requesting anonymity will be informed their identity will not be divulged. However, the individual should also be informed that in some cases, it may become necessary for the individual to reveal additional information about themselves and/or the situation in order to successfully investigate the allegation.

5.0 Retaliation
5.1 MUSC will neither discriminate nor retaliate against any individual who reports in good faith any allegation.

6.0 Requirements
6.1 A preliminary good faith inquiry will be made on any allegation. If this inquiry reveals an activity or circumstance presenting an immediate danger, the appropriate party will be notified (i.e. Risk Management, Legal Counsel, Administrator, Public Safety, etc.).
6.2 If the preliminary inquiry does not reveal an activity or circumstance presenting an immediate danger, it is necessary to determine if it is appropriate for the investigation to be conducted by the UCO or another department. If the allegation should be investigated by another department, (Risk Management, Human Resources, Office of Research Integrity, University Medical Associates, Carolina Family Care, Medical University Hospital Authority, etc.), the identified department will be notified and provided with the necessary information to conduct the investigation.

6.3 All relevant information will be collected to perform a thorough investigation. Examples of relevant information include, but not limited to: staff and management interviews, data collection, reviews of laws, regulations and policies & procedures, etc.

6.4 All interviews, meetings, reviews of laws, regulations and policies & procedures, relevant discussions and data collection will be documented and retained.

6.5 Once the investigation is complete, the appropriate individuals will be notified of the results and, if appropriate, remedial education and/or disciplinary action will be administered.

6.6 If possible and appropriate, the individual reporting the allegation will be notified when the investigation is complete.

6.7 When appropriate, policies & procedures and educational activities will be reviewed to ensure future compliance with laws, regulations and policies & procedures.

6.8 All questions and allegations will be entered into the UCO database. Data from this database will be used to generate reports on an as-needed basis.

Appendices:
Appendix A – UCO Database Fields
### DATABASE FIELDS

<table>
<thead>
<tr>
<th>Item #</th>
<th>Next sequential number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intake</td>
<td>Person receiving</td>
</tr>
<tr>
<td>Question/Allegation</td>
<td>Question or allegation</td>
</tr>
<tr>
<td>Type</td>
<td>Select category</td>
</tr>
<tr>
<td>Date</td>
<td>Date question or allegation received</td>
</tr>
<tr>
<td>Individual Reporting</td>
<td>Name of the individual</td>
</tr>
<tr>
<td>Responsible Department</td>
<td>Name of the individual’s department</td>
</tr>
<tr>
<td>Contact Information</td>
<td>Contact information of the individual</td>
</tr>
<tr>
<td>Source</td>
<td>Select correct source</td>
</tr>
<tr>
<td>Explanation of Circumstances</td>
<td>Brief explanation of the facts &amp; circumstances</td>
</tr>
<tr>
<td>Action (1-6)</td>
<td>Brief sequential synopsis of actions taken during the investigation</td>
</tr>
<tr>
<td>Resolution</td>
<td>Summary of final resolution</td>
</tr>
<tr>
<td>Violation</td>
<td>Question or allegation a violation of regulations or requirements</td>
</tr>
<tr>
<td>Method of Notification</td>
<td>How UCO was notified of the question or allegation</td>
</tr>
<tr>
<td>Hotline</td>
<td>If Hotline was used to report question or allegation</td>
</tr>
</tbody>
</table>

Appendix A
SOP 05
EXCLUDED PARTIES SCREENING

1.0 Introduction
1.1 Federal regulations require the General Services Administration (GSA) to operate an Excluded Parties List System (EPLS) and the Office of Inspector General (OIG) to operate a List of Excluded Individual/Entities. The effect of placement on these listings are contractors debarred, suspended, or proposed for debarment are excluded from receiving contracts and agencies shall not solicit offers from, award contracts to, or consent to subcontracts with these contractors, unless the agency head determines that there is a compelling reason for such action. Contractors debarred, suspended, or proposed for debarment are also excluded from conducting business with the Government as agents or representatives of other contractors.

1.2 Contractors included in the listings have been declared ineligible on the basis of statutory or other regulatory procedures are excluded from receiving contracts, and if applicable, subcontracts, under the conditions and for the period set forth in the statute or regulation.

2.0 Definitions
2.1 Ineligible Person – Any individual or entity who is currently excluded, debarred or otherwise ineligible to participate in Federal health care programs or in Federal procurement or non-procurement programs; or has been convicted of a criminal offence related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible.

3.0 New Individuals/Entities Screening
3.1 All prospective MUSC faculty, staff, independent contractors and contract vendors will be asked if they are ineligible or have been debarred from a Federal program as part of the application process.

3.2 If any individual or entity is ineligible or has been debarred, the Director, UCO will be notified prior to proceeding with the application process.

3.3 Prior to employment or contract, the name of the prospective faculty, staff or contract vendor will be screened against the listings for possible inclusion.

3.4 If the individual or entity is ineligible, they will not be employed or contracted.

4.0 Periodic Screening
4.1 Each month, the UCO will obtain a listing of all faculty, staff, independent contractors and contract vendors to be screened for determination of inclusion in the listings.

SOP 05-1
5.0 Ineligible Persons

5.1 If the screening process reveals individuals or entity as an Ineligible Person(s), they shall be removed from responsibility for or involvement with MUSC’s operations related to a Federal award or contract.

5.2 In addition, MUSC shall remove such person(s) from any position for which the person’s salary or the items/services rendered, ordered or prescribed are paid in whole or part, directly or indirectly, by Federal funding.

Appendices:
Appendix A – Excluded Parties Screening Categories
Appendix B – Excluded Parties Screening Verification Memo
## Excluded Parties Screening Categories

<table>
<thead>
<tr>
<th>Classification</th>
<th>Responsible Department for Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>MUSC New Hires</td>
<td>MUSC Human Resources</td>
</tr>
<tr>
<td>MUSC Workforce (Monthly)</td>
<td>UCO</td>
</tr>
<tr>
<td>Independent contractors and contract vendors (Monthly)</td>
<td>UCO</td>
</tr>
</tbody>
</table>

Appendix A

SOP 05-3
Excluded Parties Screening Verification Memo

Date:

From: Director, University Compliance Officer

Subj: Federal Background Check

Dear (NAME),

As part of the Medical University of South Carolina’s Compliance Plan, MUSC conducts Federal agency background checks on all employees and agents to ensure they have not been sanctioned by a Federal agency. In a recent sanction check, the name “NAME” was identified as having a sanction with the (AGENCY). Generally, these sanctions checks provide MUSC with a Social Security Number, date of birth and/or other identifying information on the sanctioned individual. However, in this instance, the only information provided was (NAME) and (ADDRESS).

Since MUSC was not provided the necessary identifying information to eliminate you as this sanctioned individual, please sign the appropriate section below and return this memo to the University Compliance Office. I apologize in advance for any inconvenience and regret we were unable to eliminate your name based on the information provided. Please feel free to contact the University Compliance office at 792-7795 with any questions.

Please sign the appropriate section:

I am not the sanctioned individual listed above and have not been sanctioned by a Federal agency.

______________________________    ________________
Signature                   Date

I am the sanctioned individual listed above.

______________________________    ________________
Signature                   Date

Appendix B
1.0 Introduction

1.1 Federal and State regulations and MUSC policies and procedures specify requirements for MUSC faculty & staff related to the accomplishment of their duties and responsibilities. In addition, many Federal and State regulations specify accomplishment of training requirements.

2.0 Requirements

2.1 It is essential for faculty & staff to complete required compliance training on an on-going annual basis. This training must be accomplished annually.

2.2 New hires must complete OSHA training prior to reporting for orientation. Other required compliance training must be accomplished within fourteen (14) days of their reporting date and all compliance training accomplished annually thereafter. The UCO will notify each new hire on the requirement to complete remaining compliance training.

2.3 The UCO will coordinate accomplishment of compliance training through the use of the departmental compliance managers. All departmental compliance managers will be given administrator access to Computerized Annual Training and Tracking System (CATTS) in order to verify the completion of training.

2.4 The UCO accepts completion of the above listed training if required to be completed by University Medical Associates (UMA) or Medical University Hospital Authority (MUHA). UMA and MUHA are responsible to ensure their employees and agents complete required compliance training.
SOP 07
INVESTIGATION OF SUSPECTED IDENTITY THEFT

1.0 Introduction
1.1 When an individual believes they are a victim of identity theft, they should report the claim of identity theft to the UCO. All potential or suspected cases of identity theft will be fully and appropriately investigated.

2.0 Requirements for Investigations
2.1 The following steps are intended to provide an outline to conduct the investigation. However, these steps are not all inclusive and additional information may be requested based upon the facts presented.

1) Request a copy of the Identification Theft Affidavit developed by the Federal Trade Commission (FTC). All supporting documentation should also be requested. An Identification Theft Affidavit recognized under South Carolina law is acceptable in lieu of the FTC affidavit.

2) Depending on the adequacy of the affidavit, or in addition to the affidavit, the following may be requested:
   a) A statement that the individual is a victim of identity theft including supporting information;
   b) A copy of the individual’s photo identification including verification of the person’s address;
   c) Any additional identification document supporting the identity theft claim;
   d) Specific information or facts supporting the identity theft claim;
   e) Any additional information supporting the individual’s claim that they did not incur the debt;
   f) Any available correspondence disputing the debt;
   g) Documentation of the individual’s residence at the time the disputed services were rendered, including copies of utility bills, tax statements, or other statements sent to the residence;
   h) Current contact information for the individual;
   i) Any information the individual may have as to the person who may have used the individual’s information;
   j) A statement from the individual verifying unauthorized use of personal information; or
   k) A statement certifying that the representation are true, correct, and contain no material omissions of fact to the best knowledge and belief of the person submitting the certification.

3) If the results of the investigation indicate the individual appears to have been a victim of identity theft, the following actions will be taken:
a) Cease collections on open accounts that resulted from the alleged identity theft. If the accounts have been referred to an outside entity for collection, the entity will be instructed to cease collections and correct any credit reports which may have resulted from the alleged identity theft; 
b) Cooperate with any law enforcement investigation relating to the identity theft;
c) Any insurance company, government program, or other payer who has made payment on the account will be notified and the appropriate refund shall be made immediately; and
d) The individual’s account/record/etc. should be flagged to indicate the identity theft occurred. If the alleged thief returns for services, the individual and law enforcement should be contacted.

2.2 If the results of the investigation indicate the individual does not appear to have been a victim of identity theft, the individual will be provided written notification they remain responsible for the bill. The notice will include the basis for the determination that no identity theft occurred.

3.0 Disposition of Medical Records When Identity Theft is Confirmed

3.1 Inaccuracies of medical records resulting from identity theft will be removed and segregated to the maximum extent possible. Any treatment related information resulting from confirmed identity theft will be removed from the medical record. The removed information will be placed in a Jane/John Doe record.

3.2 If the identity theft victim was previously seen at MUSC, the record must be reviewed to determine if treatment or payment decisions were based on erroneous information. If treatment or payment decisions related to the victim were based on erroneous information, the information must be stricken from the medical record using the normal method of correcting a medical record or the record may be amended to correct the incorrect information. Any change to the record resulting from confirmed identity theft must be linked clearly and noticeable to the erroneous information.
SOP 08
AUDITS OF GRANTS & CONTRACT ACCOUNTING DIRECT COSTS CHARGED TO GRANTS & CONTRACTS

1.0 PURPOSE AND SCOPE

1.1 Purpose and Scope

This SOP specifies the requirements for the conduct of quarterly audits of Grants & Contract Accounting direct costs charged to grants and contracts. The purpose of these audits is to determine if direct costs charged to grants and contracts were allowable, allocable and reasonable.

2.0 REQUIREMENTS

2.1 The Director, UCO and/or designated representative shall conduct the audit.

3.0 PRE-AUDIT PREPARATION

3.1 The auditor will notify G&CA and schedule a day and time to conduct the audit. G&CA will provide an electronic listing of all transactions charged to applicable grants and contracts.

3.2 The audit will be performed on a fiscal year quarterly basis of the direct charges of the previous quarter.

4.0 THE AUDIT PROCESS

4.1 The auditor shall use a random number generator and select fifty (50) direct charges to review. The auditor will also randomly select five (5) additional direct charges not selected by the random number generator.

4.2 The audit will consist of a review of documentation to confirm conformance to requirements. Examples of this documentation includes: grants, contracts, invoices, MUSC Credit Card Purchase forms, MUSC Intra Institutional Transfer Requests, MUSC Grant Transactions Reports, MUSC Request for Cost, Commitment or Encumbrance Transfer forms, credit card transaction reports, purchase orders, proof of purchases, receipts, purchase orders, etc.

4.3 The auditor shall compare documentation against the requirements specified in the MUSC Direct and Facilities and Administrative Cost Reference Table and applicable G&CA policies and procedures. The table and G&CA policies and procedures can be found in the Finance Administrative Policies and Procedures, Chapter 4 – Grants & Contract Accounting at the following website:

http://academicdepartments.musc.edu/vpfa/finance/financepolicies/index.htm
4.4 The auditor will have access to files and records to verify conformance.

4.5 An audit finding is defined as a finding violating appropriate regulations, requirements or policies and procedures.

4.6 The auditor will hold an exit briefing with G&CA. The purpose of this briefing is to discuss each audit finding.

4.7 Results of the audit will be documented and a copy provided to the Director, Grants & Contract Accounting, the Associate Provost for Research and the Vice President for Academic Affairs & Provost.

4.8 A copy of all audit reports and correspondences documenting the implementation and/or resolution of audit findings will be retained.