Symposium for Research Administrators

Reengineering Research Administration

Compliance
^
The Office

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School of Medicine Compliance Office

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Learning Objectives

- Learn about the Office of Inspector General (OIG) Compliance Program Guidance and how the School of Medicine (SOM) Compliance Program has implemented the required elements to be deemed effective.

- Learn about the mission of the School of Medicine Compliance Office (SOMCO) and how our work plan and audit scope are defined and shaped by the OIG of the U.S. Health and Human Services Work Plans, past audits, and School of Medicine Administration concerns.

- Learn what to expect during a SOMCO audit by the CRS (Compliance Review Services) or CTQA (Clinical Trials Quality Assurance) section.

- Learn about the observations noted during recent CRS and CTQA reviews.

- Learn how to be prepared for an audit by the CRS or CTQA section.

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What is Compliance?

- Doing the right thing

- Understanding your job responsibilities

- Following the rules, laws, and policies that apply to your work

- Asking questions and reporting compliance concerns

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What is the Cost of Non-Compliance?

- Loss of grant funding

- Loss of public and donor confidence and contributions

- Vulnerability to audits and lawsuits

- Large settlements/fines and corrective actions

- Administrative sanctions

- Damage to reputation

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6. Conducting internal monitoring and auditing; and

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4. Developing effective lines of communication;

5. Enforcing standards through well publicized disciplinary guidelines;

6. Conducting internal monitoring and auditing; and

7. Responding promptly to detected offenses and developing corrective action.

*Office of Inspector General *Compliance Program Guidance for Hospitals*, Federal Register, Volume 63, Number 35, Monday, February 23, 1998.

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Mission

- It is the mission of the SOM Compliance Office to lead the initiative to ensure that the SOM and the SON conduct activities, whether related to education, research or clinical, in a manner that is both consistent with regulatory, statutory and common law, and reflective of the highest ethical standards.

- The role of the office is to provide expertise, consultation and assessment in matters of compliance as well as to facilitate implementation of a "compliant culture" appropriate to an academic medical center.

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Risk areas were identified from:

– "High Risk Areas" of the OIG Work Plans

– Audit Findings and Investigational Results Occurring at Other Major Universities

– The School of Medicine's Enterprise-Wide Risk Assessment, which included Risk Ranking, received from the Departments in the SOM

– Feedback from SOM and Health System Administration

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Identified risks were evaluated based on:

- **Financial impact** the non-compliant activity would have on the University

- **Reputational impact** the non-compliant activity would have on the University

- **Probability of occurrence**

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Most Significant Risk Areas or the "Top 5"

1. Clinical Trials Billing
2. Conflict of Interest
3. Human Subject Research
4. Research Financial Compliance
5. Health Insurance Portability and Accountability Act (HIPAA)

These risk areas receive a "yearly" review.

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Additional Risk Areas

1. **Select Agents**
2. **Institutional Biosafety Committee**
3. **Anatomical Gifts**
4. **Export Controls**
5. **Institutional Review Board**
6. **CPDC Appointments**
7. **Pre-Award Office (Office of Research Administration)**
8. **Post-Award Office (Office of Sponsored Programs) (SOM Only)**
9. **Institutional Animal Care & Use Committee/Animal Welfare Assurance Office**
10. **Environmental Issues (Occupational & Environmental Safety Office)**

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SOM Compliance Office Division of Labor

- **Compliance Review Services (CRS)**
  - Research Financial Compliance
  - Highly Regulated Areas (IRB, IACUC, OESO, Select Agents, etc.)
  - Conflict of Interest Program
  - HIPAA Compliance
  - IT Security (in conjunction with the Office of Internal Audits)

- **Clinical Trials Quality Assurance (CTQA)**
  - Human Subject Research/Good Clinical Practice (GCP)
  - Clinical Trials Billing

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CRS FY13 Overview

- The majority of the initial reviews of departments, centers, institutes, and "additional risk areas" have been completed.

- Targeted re-reviews of units (departments, institutes, centers, etc.) are being conducted to determine if they are currently in compliance with corrective actions of the initial review and if they are maintaining a level of compliance in accordance with OMB Circular, NIH Grants Policy, Duke University Policies and Procedures, and the HIPAA Privacy Act of 1996.

Schedule
Research Financial Compliance (RFC) Evaluations
Departments, Institutes and Centers

2013	2014	2015
Clinical Departments • Surgery Re-review	**School of Nursing Re-review**	**Clinical Departments** • Anesthesiology Re-review • Community and Family Medicine Re-review • Pediatrics Re-review
Basic Sciences • Neurobiology Re-review	**Basic Sciences** • Biochemistry Re-review	**Basic Sciences**
Institutes and Centers • Center for Brain Imaging and Analysis • Duke Cancer Institute Re-review • Duke Global Health Institute • Heart Center	**Institutes and Centers** • Duke Translational Medicine Institute Re-review	**Institutes and Centers** • Institute for Genome Sciences & Policy Re-review

CRS Review Objectives

- Institutional compliance with corrective actions from prior review,
- Effort reporting and level of commitment,
- National Institutes of Health (NIH) salary cap and cost sharing,
- NIH Career (K) Awardees level of effort and salary,
- Administrative and clerical salaries – charges are not allowable to federal grants absent specific circumstances justification,
- Allowability and allocability of charges to federal grants,
- Cost transfers – analysis of whether these transfers are within allowable time parameters,
- HIPAA (Health Insurance Portability and Accountability Act) Privacy/IT (Information Technology) Security - assess compliance with privacy regulations,
- Endowment Funds - compliance with terms of agreements,
- Shared resources.

CRS and CTQA review
HIPAA Compliance by verifying:

- Authorization of use of Protected Health Information (PHI)
- IRB approved waivers are documented if applicable
- HIPAA training record completeness
- Research space walk-through to assess compliance with the privacy regulations
- Secure Systems Usage Memos
- Subject Reimbursement
- IT Security (in partnership with the Office of Internal Audits)

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CRS Most Common Audit Observations

- Expired Compliance Training
- Expired WBS Elements
- Improper Storage of Protected Health Information (PHI)
- Inconsistent Effort Reporting in Internal Systems
- Incorrect G/L Accounts Used to Record Salaries
- Incorrectly Certified Other Support (OS)
- Insufficient and/or Incorrect Documentation of Administrative Effort
- NIH and K Award Salary Cap Issues
- Unallowable and/or Miscoded Expenses
- Storage of Social Security Numbers Without SOM Permission
- Travel Expenses for Individuals Unassociated with the Federal Project

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HOW TO BE PREPARED FOR A CRS AUDIT

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Compliance Training

- Make sure you're receiving the monthly Compliance Exception Report, which lists individuals who are delinquent in their required compliance training.

- To be added to the distribution for your area, please contact Diane Padgett in the SOMCO.

- SOMCO reports include areas with < 95% total compliance and/or employees whose training is expired > 1 year.

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Expired WBS Elements

- Once you've submitted your close-out paperwork to OSP, follow-up with them for any outstanding issues so that close-out can occur in a timely manner.

- Continue to monitor the status of the code via CJ03 (Project/WBS Fund Code Master Data) and/or ZF600 (Sponsored Research Tracker of Past Due Closeouts) until codes say CLSD under system status.

- Keep the lines of communication open with OSP!

- GMT is also a very helpful resource!

Effort Reporting in Internal Systems

- Committed effort, cost shared or otherwise, should be properly reflected in all internal systems (Sponsored Effort System, SAP, Other Support, etc.)

Salary G/L Accounts

- At the time of a cost distribution change, review the salary G/L accounts to ensure they are appropriate for the person type (exempt, non-exempt, tenure-track, non-tenure-track, etc.) and activity (administration, instruction, research, etc.) being conducted.

- A great resource for G/L account selection is http://finance.duke.edu/accounting/glaccts/expenses/exp60xx.php

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NIH and K Award Salary Cap

- At time of award and every time a person's salary changes, review their direct charge and cost sharing amounts to ensure they are being charged appropriately.
- Financial Services provides a form to use for your NIH salary cap calculations.
- https://finance.duke.edu/research/forms-resources/forms/index.php#NIH
- K Awards are unique in that there are different salary caps set by mechanism (K01, K12, K23, etc.) and IC (NCI, NHLBI, NIDDK, etc.)
- ORA has information on K awards at http://research.som.duke.edu/research-administration/grant-administration/nih/k-award-resources
- The NIH K Kiosk has information on K awards at http://grants.nih.gov/training/careerdevelopmentawards.htm

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Other Support

- Other Support should reflect the effort as shown in multiple institutional systems.

- The current cost distribution in SAP should be reviewed in conjunction with the Sponsored Effort System for an accurate Other Support document.

Administrative Effort

- SOM Maximum Effort Policy at http://research.som.duke.edu/sites/research.som.duke.edu/files/documents/SOM%20-%20Maximum%20Sponsored%20Effort%20Policy.pdf

- Unless there is an approved waiver, all cost distributions should have effort charged to an administrative G/L (600000, 600100, 602200, 602300, 602400, 603000, 603100)

Unallowable and/or Miscoded Expenses

- Make sure you're reconciling! Reconciliation or verification of financial transactions is a key element of Duke University's internal controls and is fundamental to sound business practices.
- Review the allowability and allocability of charges as part of your reconciliation process.
- Maintain complete documentation of all charges to federal projects, including justification for allowability/allocability on these projects. Without appropriate documentation to support the expenses, charges will need to be removed from the federal projects.
- One of the elements most critical to successful financial administration of sponsored projects is the assignment of appropriate accounts to budget line items and expense transactions. Improperly-coded expenses can adversely affect a number of institutional internal monitoring controls and accounting.
- Review G/L account definitions at
  http://finance.duke.edu/accounting/glaccts/

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Travel Expenses on Federal Projects

- Any activity related to the travel should benefit the federal project involved.

- If travel expenses are reimbursed on a federal project for an individual who is not receiving salary from that project, that individual's grant-related role must be identified, documented, and kept as a part of the travel documentation.

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Shared Resources

- Know your rate(s)! Make sure you have a copy of the approved rate sheet(s).
- http://finance.duke.edu/accounting/gap/m200-300.php

Endowments

- Make sure you have a copy of the endowment agreement(s).
- If you need a copy of the agreement(s), please contact Pete Balbirnie at peter.balbirnie@duke.edu
- Read the agreement!
- Is it a professorship endowment? These have special guidelines that were published in July 2009.

Social Security Numbers (SSNs)

- SOMCO is finding SSNs on research subject payment forms, CVs, medical files from outside institutions, etc.

- Register the retention (electronic or paper) of social security numbers with the Information Security Office, or better yet, just redact them!

- http://security.duke.edu/duke-policy-ssn-usage

- http://docr.som.duke.edu/wysiwyg/downloads/ssn_security_memo.pdf

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Physical Safeguards of PHI

Paper Records

- Paper records must be stored or filed in such a way as to avoid access by unauthorized persons. Some type of physical barrier (locked door, cabinet, file drawer, etc.) must be used to protect paper records from unauthorized access.

- Paper records on desks or counters must be placed face down or concealed to avoid access by unauthorized persons.

- The theft or loss of any paper record should be reported immediately to the SOM Compliance Office.

- When not in use by authorized personnel or after business hours, documents or items containing PHI should be kept in a locked desk, locked cabinet, or other locked location.

- Limit the number of keys given to employees. Provide keys to areas and locked cabinets to only those employees whose job responsibilities require access to the areas or cabinets where PHI is stored or located.

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Physical Safeguards of PHI

Destruction of PHI

- Paper, images, and other printed materials containing PHI should be destroyed by shredding or striking out (redacting) the PHI so that it cannot be read or reconstructed.

Computer Work Stations

- Computer monitors must be positioned away from common areas, or a privacy screen must be installed to prevent unauthorized access or observation.

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Physical Safeguards of PHI

Faxes

- Confirm the fax number before faxing.
- Only the PHI necessary to meet the requester's needs may be faxed.
- A completed and signed authorization must be obtained before releasing PHI to third parties for purposes other than treatment, payment, or health care operations.
- PHI may be faxed to an individual if the individual requests access to his/her own PHI.
- All faxes containing PHI must be accompanied by a cover sheet that includes a confidentiality notice. See the DUHS Electronic Communication Policy.
- Fax machines must be located in secure areas not readily available to the public.
- Incoming faxes containing PHI must not be left sitting on or near the machine for extended periods of time.

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Physical Safeguards of PHI

Email

- Providers should not initiate any email communication that contains sensitive information.

- PHI CANNOT be included in the email subject line because the subject line is not encrypted.

- Emails that contain PHI should contain the HIPAA disclosure statement. See the DUHS Electronic Communication Policy.

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CTQA FY13 Overview

- Quarterly Subject Selection for Human Subjects
  - IRB query
  - Departmental recommendations
  - SOM/IRB requested directed reviews
  - 12 - 15 Human subject reviews per quarter

- CTQA Billing Reviews

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Selection Criteria for Human Subject Research Reviews

- Absence of external monitoring or oversight (PI initiated)
- Phase I/II Studies
- Investigator initiated Investigational New Drug (IND) or Investigational Device Exemption (IDE)
- Sponsor type (federally-funded research)
- High subject accrual
- Frequency of protocol deviations/adverse events
- Vulnerable populations (pediatrics, pregnant women, adults with diminished capacity)
- Allegations of human subjects violations or noncompliance with Federal regulations

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CTQA Human Subject Scope

- Assess adherence to the Institutional Review Board (IRB) approved study protocol, Good Clinical Practices (GCP) guidelines, and State and Federal Regulations

- Determine that the rights and welfare of human research subjects are being or have been adequately protected by the Investigator and his/her research staff

- Assess the integrity of the study data.

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CTQA Human Subject Review Objectives

- IRB Documentation
- All versions of the study protocol
- CVs for PI and Staff
- Screening/Enrollment Logs
- Delegation of Authority Log
- Correspondence and Phone Logs
- Medical Licenses (if applicable)
- Laboratory Information (if applicable)
- Test Article Accountability Logs (if applicable)
- Subject Documentation
  - Complete Case Report Forms for Each Subject Enrolled
  - Complete Source Documents for Each Subject Enrolled
  - Verification of Inclusion/Exclusion Criteria

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CTQA Most Common Human Subject Findings

- Protocol deviations that need to be filed
- Informed consent process issues
- Missing data elements and/or case report form omissions/errors
- Missing original consent forms
- Incomplete or missing signature and delegation of authority logs
- Sample/test article storage/collection issues
- Subject eligibility (inclusion/exclusion criteria)
- HIPAA related findings

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How to be Prepared for a CTQA Audit

Keep your files organized!

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Keep your files organized!

- Regulatory
  - Protocol (all versions)
  - Investigator Brochure (all versions)
  - Protocol Amendments
  - FDA Form 1571/1572 (all versions)
  - Investigator Agreements
  - CVs for PI and Staff
  - Medical Licenses
  - IND/IDE Documents
  - Enrollment/Screening Logs
  - Delegation of Authority Log
  - Drug Package Insert (if applicable)

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Keep your files organized!

- IRB Files
  - Approval Letter for Initial Protocol with Original Consent Form
  - All Continuing Review Approval Letters and Original Updated Consent Forms
  - All Amendment Approvals
  - All Versions of Consent Documents for Screened and Enrolled Subjects
  - All Status/Progress Reports for:
    - IRB Approved Renewal(s)
    - Adverse Events
    - Deaths
    - Study Termination
    - Final Summary

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Keep your files organized!

- Correspondence and Phone Logs
  - All Sponsor Correspondence
  - All CRO Correspondence (if applicable)
  - All FDA Correspondence
  - All IRB Correspondence
  - Monitoring and Auditing Logs

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Keep your files organized!

- Laboratory
  - Laboratory Certification and Normal Ranges
  - Up to Date CV of Laboratory Director

- Research Test Article Accountability
  - Receipt Log
  - Dispensing Log
  - Return and Destruction Log
  - Storage Temperature Log

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Keep your files organized!

- Subject Documentation
  - Complete Case Report Forms for Each Subject Enrolled
  - Complete Source Documents for Each Subject Enrolled
  - Verification of Inclusion/Exclusion Criteria
  - When did activities occur and were these within protocol window?

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CTQA Billing Compliance Review

CTQA Reviews:
  – Subject Billing Registry (formerly Web Registry)
  – Charge Assignment Grids
  – Bill Hold Status
  – Work Breakdown Structure elements (fund codes) between Charge Assignment Grids and Subject Billing Registry

CTQA Verifies:
  Enrollment Log, Subject Billing Registry and IDX for date and timeliness of entry

CTQA Examines:
  Charge Assignment Grids and compares them to:
  – Protocol and Schedule of Events
  – Informed Consent
  – Budget
  – Contract/Grant

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CTQA Most Common Billing Review Findings

- Subjects not entered into the subject tracking system
- Subjects not entered into the subject tracking system within one business day
- Subjects not logged into IDX
- Consent and/or end of billing dates do not match between enrollment log, subject tracking system and IDX
- Corrections required on charge assignment grids

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SOM Compliance Office
Advisory Role

We're not just about Human Subject/Billing Reviews, Research Financial Compliance, or Other Risk Areas:

- A Source of Information and Guidance on Compliance Areas

- Prevention of Future Compliance Problems through Education

- Educational Compliance Reviews

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Duke University School of Medicine Compliance Office

July 11, 2012

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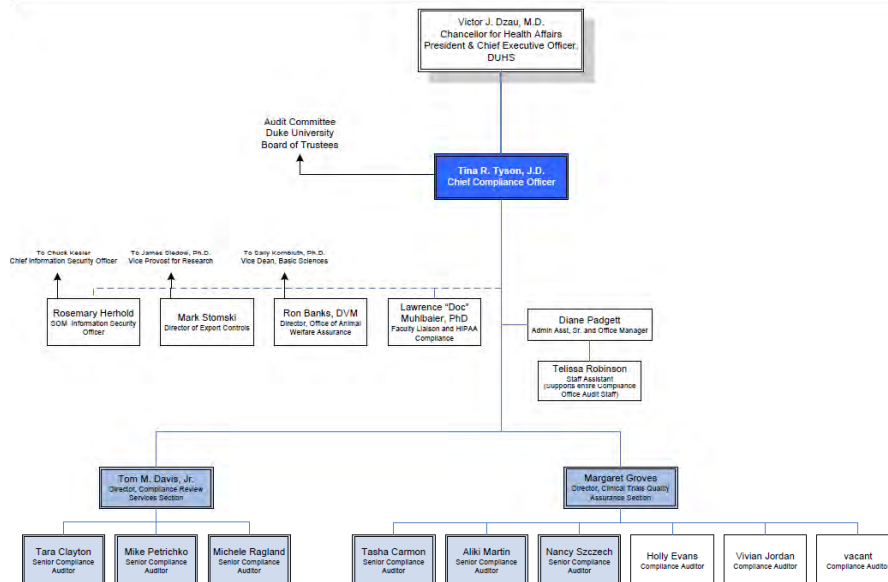
Compliance Office Contact Information

Tina R. Tyson, JD, Chief Compliance Officer, tina.tyson@duke.edu

Administrative Services
  Diane Padgett, Senior Administrative Assistant, diane.padgett@duke.edu
  Telissa Robinson, Staff Assistant, telissa.robinson@duke.edu

Clinical Trials Quality Assurance and Billing Compliance, clinica4@dm.duke.edu
  Margaret Groves, Director, margaret.groves@duke.edu
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  Mike Petrichko, Senior Compliance Auditor, michael.petrichko@duke.edu
  Michele Ragland, Senior Compliance Auditor, michele.ragland@duke.edu

Reporting Compliance Concerns

The Integrity Line: 1-800-826-8109

- Compliance concerns can be reported anonymously

- Non-retaliation and non-retribution policy

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Questions? What can we do to help you?

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