



Annual Research Administrator's Symposium 2016

The Office of the Vice Chancellor for
Research - Compliance Program

Robin Cyr – Associate Vice Chancellor for
Research, Research Compliance Officer



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

What is Research Compliance?



- Research compliance is a comprehensive program that helps our institution and the personnel involved in research ensure that we conduct our operations and activities ethically; with the highest level of integrity, and in compliance with legal and regulatory requirements.



Why do we need a research compliance program?



“An effective compliance program addresses the Government’s and research community’s mutual goals of ensuring good stewardship of Federal funds by eliminating erroneous or improper expenditure of Federal research funds, improving administration of grants (both from the Federal Government and from private sources), and demonstrating to employees and the community at large the institution’s commitment to honest and responsible conduct.” *

*** Source – 70 Federal Register 71312 (Office of the Inspector General DHHS)**



Ok, but why is it important for us to have a research compliance program?

- The UNC Board of Trustees – enhanced visibility / accountability of the risks and measures taken to mitigate
- Accreditation and Auditor – Demonstrates our commitment to excellence and exercising appropriate stewardship through sound internal controls.
- Sponsors and Donors – assures them of oversight and stewardship of the funds they provide.
- Recruitment of Faculty and Students – protecting the reputation of the university so we can continue to attract the best research faculty and staff as well as the best and brightest students for our programs.
- Protect the reputation of the research enterprise and safeguard the trust of our sponsors and collaborators.



U.S. Federal Sentencing Guidelines §8B2.1(a)(2)



- To have an effective compliance program, an organization must establish and maintain an organizational culture that “encourages ethical conduct and a commitment to compliance with the law.”



Our Chancellor has demonstrated her commitment!

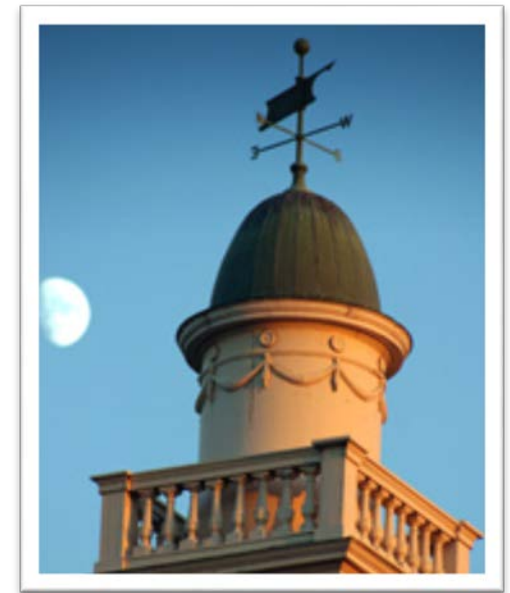


- In May of 2015, Chancellor Folt convened two working groups
 - The Policy and Procedure Working Group was charged to design and oversee an institution-wide review of policies and procedures, develop recommendations for improvement and create a mechanism for periodic reevaluation.
 - The Ethics and Integrity Working Group was charged with examining how the university might strengthen its commitment to ethics and integrity and offer their recommendations.
 - The two groups submitted their final reports in November of 2015 and the outcome of their efforts yielded the new office of Ethics Education and Policy Management.
 - On July 21, 2016, the Chancellor announced that Dr. Kim Strom-Gottfried has agreed to serve as the Director of the new office. This is a cabinet-level position and in it Dr. Strom-Gottfield will focus on coordinating the ethics programs and reporting mechanisms and oversee the management of the University's policy infrastructure.



Elements of an effective compliance program*

1. Implementing written policies and procedures,
2. Designating a compliance officer and compliance committee,
3. Conducting effective training and education,
4. Developing effective lines of communication,
5. Conducting internal monitoring and auditing,
6. Enforcing standards through well- publicized disciplinary guidelines,
7. Responding promptly to detected problems and undertaking corrective action, and
8. Defining roles and responsibilities and assigning oversight responsibility.



* Source – 70 Federal Register 71312 (Office of the Inspector General DHHS)



Implementing written policies and procedures

- New policies in draft form include:
 - PI Eligibility
 - PI Responsibilities
 - Sponsored Projects Code of Conduct
 - Institutional Base Salary
 - Fixed Price Agreements
 - Overdraft and Deficit Account Monitoring
 - Subaward Risk Assessment and Monitoring



All other OSR policies are being updated as are the policies and procedures for COI, OACU and OHRE. Target communication and rollout is this fall.



Designating a



officer and compliance committee

“OIG recommends that a compliance committee be established to advise the compliance officer and assist in the implementation of the compliance program. If structured appropriately, the committee can provide the compliance officer with contacts in various parts of the institution and the names of individuals who possess subject matter expertise.” *

* Source – 70 Federal Register 71312 (Office of the Inspector General DHHS)



Designating a compliance officer and compliance committee, continued....

Meet the Research Compliance Steering Committee

- Brian Bertlshofer, Director of Cost Analysis - OSR
- Joy Bryde, Conflict of Interest Officer
- Valorie Buchholz, Quality Assurance Program Manager - OCT
- Nina Cannon, Director of the Office of Industry Contracting
- Judy Faubert, Associate University Counsel
- Tracy Heenan, Director of the Office of Animal Care and Use
- Micki Jernigan, Chief Privacy Officer
- Andy Johns, Interim Director of the Office of Sponsored Research (OSR)
- Elizabeth Kipp-Campbell, Director of the Office of Human Research Ethics
- Mary Beth Koza, Director of Environmental Health and Safety
- Carolyn Marlow, Assistant Dean – SOM Sponsored Programs Office
- Christine Nelson, Director of the Office of Clinical Trials (OCT)
- Jackie Quay, Director of Licensing and Innovation Support
- Leeanne Walker, Director of Compliance and Research Integrity – SOM
- Phyllis Petree, Director of Internal Audit
- Lisa Ross, Research Compliance Training Specialist
- Robin Cyr, Research Compliance Officer



Conducting effective training and education

New Training Program Coming This Fall!



- With the retirement of the Tar Heel Certificate Program, we need a new training program
- An arrangement has been made with another large research university to obtain their training program and adapt it for use on our campus
- An Advanced Training Specialist has been hired and will start on August 22nd (Thank you to the interview committee)
- Dr. Lisa Ross will be joining the Research Compliance Program and will begin working on the new training program
- Lisa brings over 15 years of experience as an independent education consultant; more than 7 years of experience in higher education which includes curriculum design and instruction

“The institution needs to establish a mechanism to ensure that employees receive the training they need. Training could be made a condition of continued employment and failure to comply with training requirements could result in disciplinary action. Adherence to the training requirements as well as other provisions of the compliance program should be a factor in the annual evaluation of each employee.” *

* Source – 70 Federal Register 71312 (Office of the Inspector General DHHS)



Developing effective lines of communication



- This is the email address for the research compliance program. You can use it for questions or to let me know of a concern that you may not be ready to report through the compliance line. research_compliance@unc.edu
- By all means use this address if you think of a topic that we need to address in a training or with some other type of communication including a policy or SOP.

“Open lines of communication between the compliance officer and employees are equally important to the successful implementation of a compliance program. In addition to serving as a contact point for reporting problems and initiating appropriate responsive action, the compliance officer should be viewed as someone to whom personnel can go for clarification on the institution’s policies.” *

* Source – 70 Federal Register 71312 (Office of the Inspector General DHHS)

IF YOU SEE SOMETHING, SAY SOMETHING





The UNC – CH Compliance Line

- The Compliance Line is an option for making a confidential report using either the internet or a telephone line to help the campus community identify and address compliance concerns in a positive, constructive environment.
- This internet and telephone reporting service is not maintained on the University’s systems and is not maintained by University employees. Reports can be filed anonymously and the reports are held securely and confidentially on the external systems.
- EthicsPoint, based in Portland, Oregon, is the commercial service provider for the University’s Compliance Line. This commercial service provider was chosen for the quality and security of its service after careful review of several vendors’ proposals.
- University Compliance Line internet access:
https://secure.ethicspoint.com/domain/en/report_custom.asp?clientid=13027
(See left hand menu “To Make a Report” or click on “Follow-up on a Report”)
- University Compliance Line telephone access: **1-866-294-8688.**

To Make a Report

Please choose the appropriate category from the list below:

- [Financial](#)
- [Research](#)
- [Environment, Health and Safety](#)
- [HIPAA](#)

If your report concerns the activities of a foundation affiliated with the University of North Carolina at Chapel Hill, please select the applicable foundation from the menu below:

- Select Affiliated Foundation -

Submit

Or to place a report by telephone call 866-294-8688 (toll free).



Yes, BUT...

I could get in trouble or lose my job if I do that.....

- University policy and state law prohibit retaliation or reprisal against an individual for reporting in good faith a violation of state or federal law, rule or regulation. <http://policies.unc.edu/policies/protect-reporting/>
- Reports through the Compliance Line are entered directly on the EthicsPoint secure server to prevent any possible breach in security. EthicsPoint makes these reports available on the EthicsPoint system only to specific individuals at the University who are charged with evaluating the type of problem and location of the incident, and who understand the importance of maintaining confidentiality.
- The EthicsPoint system and staff are trained and committed to ensure that no report is shared with implicated parties, their peers, or subordinates.
- No report is shared with implicated parties, their peers, or subordinates. An individual who has filed a concern report through the Compliance Line website or phone number receives a unique user name and chooses a password.

“For a compliance program to work, employees must be able to ask questions and report problems.....Research institutions should consider the adoption of open-door policies to foster dialogue between management and employees. To encourage communications, confidentiality and non-retaliation policies should also be developed and distributed to all employees.”

*** Source – 70 Federal Register 71312 (Office of the Inspector General DHHS)**



Conducting internal monitoring and auditing



- From the Internal Audit Department home page:
- *“The Internal Audit Department is a service unit established to assist management of the University of North Carolina at Chapel Hill in providing the highest quality education and services to students and the people of North Carolina. The underlying premise of our work is that the University, as a leader in the dynamic environment of higher education, must function at the highest level possible.*
- *Internal Audit supports this objective by providing independent, proactive analyses of operations, financial activities, and systems of internal control. The purpose of these analyses is to evaluate whether resources are used in keeping with State requirements and the University’s mission, goals, and objectives.”*
- The Research Compliance Program is partnering with the Internal Audit Department to ensure that we are meeting the internal control requirements as set forth in the Uniform Guidance § 200.61, §200.62, §200.303, §200.430, § 200.507 through inviting the Director of Internal Audit to serve as a member of the Research Compliance Steering Committee.

“The identification of risk areas is an important aspect of formulating policies and procedures, developing a training and education program, and conducting internal monitoring and audits.” *

* Source – 70 Federal Register 71312 (Office of the Inspector General DHHS)



Enforcing standards through well- publicized disciplinary guidelines.



“In addition to a clear statement of detailed and substantive policies and procedures, OIG recommends that institutions that receive PHS research awards develop a general institutional statement of ethical and compliance principles that will guide the institution’s operations. One common expression of this statement of principles is the code of conduct. The code should function in the same fashion as a constitution, i.e., as a document that details the fundamental principles, values, and framework for action within an organization. The code of conduct for research institutions should articulate the institution’s expectations of commitment to compliance by management, employees, and agents, and should summarize the broad ethical and legal principles under which the institutions must operate.” *

*** Source – 70 Federal Register 71312 (Office of the Inspector General DHHS)**



Enforcing standards through well- publicized disciplinary **GUIDELINES**



The Research Division will be introducing our new Sponsored Projects Code of Conduct this fall. Doing so will help clarify the standards that we are expected to uphold, here is a glimpse at that new draft policy:

- The University of North Carolina at Chapel Hill is one of the leading public research universities in the nation. The University is committed to maintaining the integrity and validity of the academic research conducted by faculty, staff and students. UNC-CH therefore holds to the fundamental belief that research should be conducted and the results of research disseminated, honestly, accurately and in accordance with the highest of professional standards.
- Therefore, it is essential to promote an environment that facilitates the UNC-CH research community's ability to do their best work, be respected, and have a positive experience while at the University. To that end, the purpose of the Sponsored Projects Code of Conduct is to promote and communicate the University's commitment to these guiding principles and to the highest standards of ethics and integrity for faculty, staff and students undertaking research.



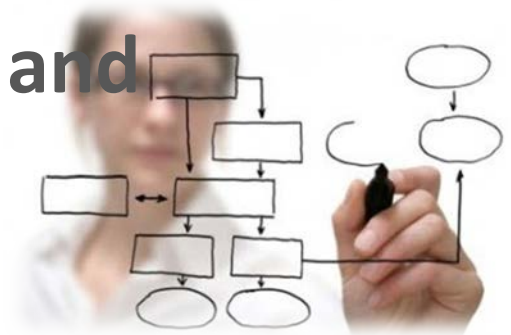
Responding promptly to detected problems and undertaking **CORRECTIVE ACTION**

- Determine if the problem stems from weak internal controls, a change in regulations or procedures that warrant a new control measure or an area in which we need additional guidance and training.
- Determine if the issue warrants reporting to a sponsor or a regulatory body.
- Ensure that the appropriate representation are involved to develop an effective and realistic corrective action plan (CAP).
- Work with OUC, IA and applicable research support office to make sure that the CAP is clear, addresses the issues noted and will prevent reoccurrence of the original problem when implemented.
- Determine if the issue is isolated or systemic and develop a communication plan that will include the department, unit or entire research community.
- Conduct periodic follow up reviews to ensure that the CAP was implemented accurately, was effective and is sustainable.

*Corrective action should not be seen as punitive or as a criticism but rather as an opportunity to improve and strengthen our program! 😊



Defining roles and responsibilities and assigning oversight responsibility



- The policy and procedure revision work that is underway will help clarify roles and responsibilities.
- The procedures will no longer be incorporated in to the policy documents.
- Each policy will refer to a corresponding standard operating procedure (SOP).
- Each SOP will clearly delineate the roles and responsibilities over the full life cycle of the award or protocol.
- In addition, there is a new PI Responsibilities Policy draft that is currently under review.



About our Research Compliance Program

- The University of North Carolina Research Compliance Program is committed to advancing the highest standards of ethics, integrity and honesty, and to compliance with all applicable laws, regulations and policies governing research, privacy and conflict of interest.
- The Program strives to promote best practices and ethical behavior and to deter activity contrary to these standards by (a) anticipating risk, and (b) encouraging strong stewardship and management accountability at all levels, in collaboration with institutional colleagues responsible for compliance implementation.





Compliance Program Objectives

- Anticipating, analyzing and communicating current compliance standards to the campus leadership, research communities and departments that support them
- Providing oversight of and assistance with development of policies and procedures to ensure protection of human and animal study subjects and appropriate stewardship of funds
- Providing structure for disclosure and management of conflict of interest
- Fostering collaboration among institutional and administrative leaders with compliance responsibility to address issues that transcend departments through communication, training and integrated processes.
- Providing leadership, coordination and assistance with the management of agency reviews, audits and investigations
- Receipt, analysis and resolution of expressions of concern (“whistleblower” communications), including those processed through the confidential hotline





Since the beginning of the calendar year we have been renewing our commitment!



- Compliance is vital, and we are committed to the responsible conduct of research and the accurate and complete documentation of research.
- We are revising our policies and procedures and encourage compliance by providing support, training and educational resources to our faculty and staff.
- To further our commitment to appropriate conduct, we are adopting new policies and procedures to address research compliance, including a new Research Code of Conduct.
- We encourage all faculty and staff to report any noncompliance or violation of law or policy including false claims for payment of government funds.
- It is the duty of all faculty and staff to report job-related criminal conduct of which they have actual knowledge or job-related situations that endanger the health and safety of any individual.



It's more than just print, post and pray



- To be effective, our compliance program must be a vital, integrated element of our work and the way we do it. We have to ensure that all employees know how to uphold ethics and compliance standards in their work.

The hallmarks of an effective ethics and compliance program are:

- Freedom to question management without fear;
 - Rewards for following ethics standards;
 - Not rewarding questionable practices, even if they produce good results;
 - Positive feedback for ethical conduct;
 - Employee preparedness to address misconduct; and
 - Employees' willingness to seek ethics advice.
- **Leadership happens at all levels.** You shape your everyday environment through the way you conduct yourself on the job. To have a sound research compliance program, we all have to work together. Research compliance is definitely a team effort!



- Thank you for attending this session, I sincerely appreciate your desire to learn more about our research compliance program!
- If you have questions or suggestions, don't hesitate to contact me.
 - My office is located in Bynum Hall in Room 301A
 - You can email me at robin_cyr@unc.edu
 - Call me at 919-962-8756

