



Research Compliance Update

November 9, 2016



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

Research Compliance Officer

- Advance the research mission through coordinating federally and locally mandated compliance regulations governing sponsored research
- Oversee the Office of Human Research Ethics, the Office of Animal Care and Use and the Conflict of Interest Program
- Lead the Research Compliance Steering Committee
- Serve as the policy liaison for the Research Division
- Oversee the development and implementation of a comprehensive research administration training program for administrators and faculty
- Serve as the institutional representative for the Council on Government Relations (COGR) and the Federal Demonstration Partnership (FDP)
- Conduct due diligence reviews in response to reports of possible non-compliance in research



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) and the US Sentencing Guidelines



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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 later this winter.



Designating a compliance 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....

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
- Lisa Ross, Research Compliance Training Specialist
- Robin Cyr, Research Compliance Officer
- Phyllis Petree, Director of Internal Audit (Advisory capacity to the committee)



Conducting effective training and education

New Training Program Development



- With the retirement of the Tar Heel Certificate Program, we need a new training program.
- In August, Dr. Lisa Ross joined the Research Compliance Program and is establishing a campus network that she will work with to develop our 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



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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).



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Conducting internal monitoring and auditing



- OSR Cost Analysis and Compliance team does recharge center initial business plan and fee review with continued biennial reviews; effort reporting; subrecipient monitoring activities and post-audit review of selected items of cost
- OCT quality assurance program audits
- Conflict of Interest monitoring activities and required disclosure
- Annual continuing reviews of current protocols – IACUC, IRBs and IBC
- Follow up on inquiries or reports submitted via the research compliance mailbox or EthicsPoint, audit and/or monitor as warranted
- Internal Audit activities

“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)**



Up and Coming.....



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.





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, individual and organizational
- 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



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!



- 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[®]

