411
Compliance

Records Management at UAB

Effective records management is a comprehensive, ongoing process and includes a current policy, retention schedule, destruction guidance, data security procedures, and appropriate consideration of litigation holds and other legal/regulatory requirements. The *UAB Records Retention Policy* requires all UAB operating units to institute an appropriate records management program for the records they create and maintain. This article is the first in a series intended to raise awareness of relevant records management issues and provide guidance and best practices to units in implementing requirements. In this issue, we will highlight the *UAB Records Retention Schedule*.

An important initial step in managing records at UAB is to inventory your department's or organization's records using the *UAB Records Retention Schedule*, which is consistent with the *Functional Analysis and Records Disposition Authority*, approved by the Alabama State Records Commission for Public Universities of Alabama. The records retention schedule lists UAB records by major category. For each specific record identified within category, a *minimum* retention period – that is, the shortest amount of time a record must be retained – and the responsible UAB business unit is listed. The minimum retention periods can be also viewed as the time when disposing of a record can *first* be considered.

There are currently ten major categories of records listed in the *UAB Records Retention Schedule*:

- **Administrative:** Records documenting the general administration of each office or activity within a college. Examples: accreditation files, annual reports, policies and procedures, meeting minutes and agendas.
- **Athletics:** Records of the athletics program, many of which are created to meet NCAA requirements.
- **Student Education:** Records of student activities, student services, financial aid, admissions, registration, and academic progress. Examples: Student government association records, student permanent records, grade and course credit records, requests for transcripts, and financial aid files. Sub-categories are:
  - Admissions Data/Documents for Applicants Who Do Not Enter
  - Admissions Data/Documents for Applicants Who Enroll
  - Registration and Attendance/Academic Progress Records
  - Certification Data/Documents
  - Publications, Statistical Data/Documents, and Institutional Reports
  - Family Educational Rights and Privacy Act (FERPA) Data/Documents
  - Federal Student Financial Aid (SFA) Records
- **Finance/Fiscal:** Records documenting the financial activity of the university.
- **Legal:** Records documenting the university's legal obligation to another party and legal counsel records.
- **Human Resources:** Records of personnel activities of the university.
- **Public Relations:** University public information and media materials and records of public events.

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Objectives of *Compliance 411*:
- To raise awareness
- To communicate important developments
- To foster transparency

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New Initiative to Assess Campus Experience for Visiting International Scholars and Scientists

The President's Risk Cabinet has recently chartered a taskforce to address onboarding, support, and mentoring for visiting international scientists and scholars on campus. The initiative will begin with a process to identify potential vulnerabilities and opportunities for improvement, with the intended outcome being assurance that visiting international scholars' and scientists' UAB experience meets their goals and UAB Enterprise Code of Conduct expectations for quality, respect, compliance, and safety.

A major part of the taskforce's work will include identifying what is currently working well and areas needing greater attention in UAB's culture and processes for visiting international scientists and scholars, including performing a gap analysis of the current working environment, identifying best practices of peer institutions, and enhancing oversight, mentor training, and avenues for visiting scholars to obtain support.

Championed by Provost Pam Benoit, Vice President for Research Chris Brown, and Chief Human Resources Officer Alesia Jones, the taskforce includes representatives from Student Affairs, Human Resources, the University Compliance Office, Research Administration, The Graduate School, Research Integrity, and areas of international concern such as International Student & scholar Services, Sponsored International Programs, and International Medical Education. Teresa Bragg, University Compliance Officer, facilitates the committee.

For more information on the work of this taskforce, contact Katie Crenshaw at kcrenshaw@uab.edu.

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- **University Police:** Records of law enforcement activity on the university campus.
- **Facilities:** Records documenting the general administration of university real properties and facilities.
- **Research:** Records related to research awards to recipients, Public Health Service Awards, Federal Drug Administration, and HIPAA Privacy rule related to research.
- **Patient Records:** Patient medical records for all UAB schools that have clinical operations.

Questions about records relevant to your unit or about records retention periods should be directed to your immediate supervisor or department administrator. The University Compliance Office is available for consultation as needed.

Compliance Challenge

Read the hypothetical scenario below, and click on an answer to enter a drawing for one of two $10.00 Barnes & Noble gift certificates to be held April 2, 2018. You don't have to select the right answer to be entered into the drawing; you only need to participate. Only those with addresses ending in uab.edu or uabmc.edu qualify.

Dr. Frank had recently accepted his first teaching position at UAB and was instructing a course in American literature. As he was grading essays, he noticed that one student's paper appeared to be very similar to that of another student in the same class, leading Dr. Frank to suspect that at least one student, or possibly both students, had plagiarized. After reviewing the papers, he confirmed that the majority of the text in both papers was identical. As a new instructor, Dr. Frank was somewhat familiar with the University's academic policies, but was unsure exactly which to consult given the situation.

Where would Dr. Frank find UAB's current process for addressing academic misconduct and options for imposing consequences?
- A. *Policy on the Responsible Conduct of Research and Other Scholarly Activities*
- B. *Academic Honor Code* and the school- or program-specific academic code
- C. *Student Conduct Code*
- D. Alabama Ethics Law

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University Leadership Engagement Advances Continuous Process of Risk Mitigation

In 2013, in collaboration with leadership from each school/college, the University Compliance Office (UCO) began the formal process of strategic risk assessment, mitigation planning, and monitoring. Since then, UCO's partnership with the schools' Executive Risk Oversight Committees (EROCs) and central units has resulted in the successful attainment of goals in a risk mitigation program designed to reduce the likelihood and impact of noncompliance in priority areas of the schools/college and University as a whole, including

- Grant management and effort reporting;
- Conflicts of interest and commitment;
- Information governance/data security/privacy; and
- Responsible conduct of research.

In November 2017, UCO renewed the process beginning with a refreshed risk assessment with the School of Health Professions. As of March 12, UCO has completed this initial phase of the process by leading refresh workshops with all nine schools and the college. Included in each workshop were discussions of how well each school did in achieving goals set for their previously determined risk areas and leaders' informed perceptions of the emerging risks they currently face.

The results of each workshop will be compiled into an updated risk profile for each school and for the University at large. Just as before, the President's Risk Cabinet will review aggregate data and define the University's priorities, and each school will develop their own risk mitigation plan to address them. The result will be a compliance risk mitigation dashboard elevating common concerns and focusing institutional resources on reducing risks that affect UAB as a whole.

Having achieved success by integrating a consultancy model for school/college interaction, accountability of school/college EROCs, and a dashboard approach to reaching milestones and measuring results, UCO and its school partners will advance continuous process improvement through awareness of risk and leadership engagement in management of risk.

Got Policy?

Is your unit considering development or revision of a policy, handbook, or manual affecting employees, students, or other University community members? If so, be aware that a new rule adopted by the Board of Trustees at its November 2017 meeting may require UA System Office review and approval prior to publication to the UAB Policies & Procedures Library and implementation. As a matter of best practice, policymaking units should generally conduct benchmarking with peer and sister institutions, in addition to consulting with affected stakeholder groups and Office of Counsel, to assure the final written product is of greatest quality and consistent with other University positions on the topic. Now, as an added step, policies, handbooks, manuals, and other guides may also need to be vetted at the system level. For more information, contact Katie Crenshaw in the University Compliance Office at kcrenshaw@uab.edu.

Congratulations to Compliance Challenge Winners!

Congratulations to Fall 2017 Compliance Challenge winners Angela Stowe and Paula Clawson. By participating in the Compliance Challenge, they were entered into a drawing, and each won a $10.00 gift certificate. To participate in this month's Compliance Challenge and enter a drawing for one of two $10.00 Barnes & Noble gift certificates, see page 2.

Student Health and Wellness Director of Student Counseling Services and Wellness Promotion Angela Stowe, PhD, shows off her Lucy's Coffee gift certificate. Not pictured is UAB Huntsville Regional Medical Center's Paula Clawson, who won a Barnes & Noble gift certificate.

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Non-Compliance Can Have a Major Financial Impact

In February, the U.S. Attorney's Office announced that the University of North Texas Health Science Center (UNTHSC) has agreed to pay $13 million to settle claims that it had inaccurately measured, tracked, and paid researchers for effort on NIH grants. Specifically, flaws in time and effort reporting practices, including failures to accurately and timely certify, were identified in nearly 120 NIH-funded research projects during the years 2011-2016.

In addition to the settlement, UNTHSC has invested significantly to revamp its system of federally-funded research tracking and assure greater compliance and accountability. Some of the restructuring of UNTHSC internal controls include:

- Effort reporting deadline escalation reminders to leaders from PIs up through provost's office;
- Mandatory training for employees with a required passing score of 100%;
- Expanded review of payroll documents;
- Software and data system upgrades;
- Implementation of enhanced monitoring processes;
- Increased availability of best practices documents; and
- Five (5) new hires and reassignment of ten (10) existing employees within research administration and compliance.

UAB has recently re-evaluated and updated its effort reporting procedures in an initiative to ensure compliance with federal requirements and mitigate the potential for negative audit findings and financial penalities. If you have questions about effort reporting, contact your Departmental Effort Officer, or visit the University Compliance Office's Effort Reporting webpage.

NSF Adds Stipulations to Grantee Anti-Harassment Requirement

In 2016, the National Science Foundation (NSF) asserted their ability to "terminate funding to any institution found to be in non-compliance with Title IX regulations." On February 8 of this year, NSF further stipulated to university presidents that sexual harassment by any grantee personnel be reported to NSF. The notice states: "NSF has developed a new award term and condition that will require grantee organizations to report findings of sexual harassment, or any other kind of harassment regarding a PI or co/PI or any other grant personnel." From now on, they will also require notification if the awardee institution places a PI, co-PI, or other grant personnel on administrative leave due to findings or investigations of violations of organizational codes of conduct or institutional harassment/sexual harassment policies. Once notified, NSF's options for response or sanction could include suspension of research funds or a requirement that the grantee institution replace or remove the personnel. The NSF notices on harassment can be found here.

UAB's Code of Conduct and policies on Title IX, Equal Opportunity and Discriminatory Harassment and Duty to Report and Non-Retaliation reinforce such efforts on the part of the scientific community to foster safe, productive research and education environments for current and future scientists and engineers. For more information on Title IX and related subjects, visit the webpages of the UAB Title IX Office or Office of Diversity, Equity, and Inclusion.

UNIVERSITY COMPLIANCE OFFICE *Areas of Focus*

Access information on these University Compliance Office areas of focus by clicking on a topic below:

Alabama Ethics Law
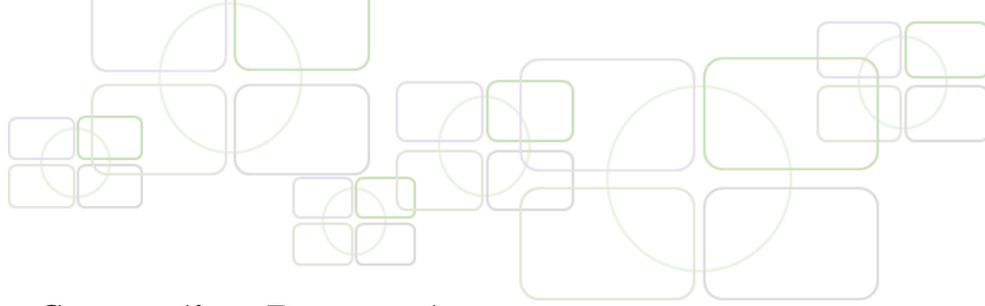Effort Reporting
External Activities
International Travel
University Policy Review & Development

Conflicts of Interest/Commitment
Export Control
Federal Open Payments Law
Records Retention

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NIH Single IRB Policy Helps Streamline Research

While the single Institutional Review Board (sIRB) model has been in use for multi-site studies for many years, it was not until recently that it became a requirement of NIH-funded research. This policy applies only to multi-site studies where the same protocol involving non-exempt human subjects research is used across all sites. It will enable research to proceed as quickly as possible without compromising ethics and protections for human participants, reduce administrative burden, and help prevent systemic inefficiencies and inconsistencies. The requirement does not apply to awards made prior to January 25, 2018; however, for all proposals submitted on or after January 25, 2018 , as well as all competing grant applications with due dates on or after January 25, 2018, the use of a single IRB is required.

There are both policy-based and time-limited exceptions. When Federal, State, Tribal, and local laws, regulations, and policies require local review, an exception is made and does not require NIH Exceptions Review Committee approval. An exception for local review can also be made when there is a compelling justification; NIH expects such cases to be rare and approved by the NIH Exceptions Review Committee. If an ancillary study is part of an ongoing study or parent study, sIRB is not required until the parent study is expected to comply with the sIRB requirement, i.e., the January 25, 2018 or first competing renewal thereafter.

The terms "single IRB" (sIRB) and "central IRB" (cIRB) are often used interchangeably. Some organizations may differentiate between the two terms by using single IRB to refer to the IRB reviewing for multiple sites participating in a single study, while the term central IRB can refer to the IRB reviewing for all sites participating in multiple studies conducted by a network or consortium.

While the term "IRB" is often used generically to encompass the entire human research protection program, it is important to note here that single IRBs only fulfill the responsibilities of the board itself. Regulations governing human subjects protections spell out both board and broader institutional responsibilities. The UAB Office of the IRB (OIRB) is responsible for many of these institutional responsibilities. **As such, it is imperative that the UAB OIRB is still involved in the review process, even if the single IRB is at another institution. The**

UAB OIRB will ensure other ancillary approvals (e.g., financial conflicts of interest, pharmacy, radiation safety, and clinical billing) are in place.

The agreement that formalizes the relationship between a site relying on an external IRB and the IRB reviewing the research is called an IRB Authorization Agreement or IAA. This agreement may also be called a reliance agreement or memorandum of understanding. The type of agreement required for a particular single IRB arrangement depends on the institutions involved. The SMART IRB agreement is a reciprocal reliance agreement that has been executed by many institutions, including UAB. This reciprocal agreement precludes the need to negotiate stand-alone agreements with each site for every study, which can represent a major hurdle to the single IRB process.

Two of the independent IRBs that have been identified by the UAB OIRB for single IRB reviews — Schulman IRB and Quorum IRB — are both signatories to the SMART IRB agreement. Western IRB (WIRB) is not a signatory to the SMART IRB agreement. If WIRB is the reviewing IRB, every site must have an agreement in place with WIRB for the reliance arrangement. The UAB IRB encourages the use of the SMART IRB agreement as much as possible since much of the effort in starting a single IRB arrangement is the negotiation of the agreement with all participating sites.

The selection of the single IRB is primarily the responsibility of the lead site. If UAB is the lead site, the investigator should reach out early to the team of UAB OIRB staff members who coordinate the single IRB process to discuss the study. When selecting a single IRB, there investigator should consider several factors including an IRB's levels of experience and expertise related to the investigation under review and its capacity for a larger number of participating sites. An investigator's familiarity with an IRB's processes, as well as the existence of an already executed reliance agreement will help to facilitate the review. It is important that the investigator also consider the costs associated with the review and build those charges into the study budget at the time of proposal development.

For more information, visit the UAB IRB's webpage on Single IRB, or see the full NIH policy here.

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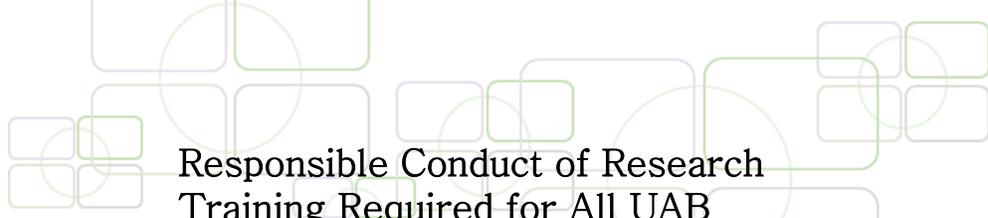
Responsible Conduct of Research Training Required for All UAB Undergraduates Conducting Research

UAB's proactive approach to training in the area of Responsible Conduct of Research (RCR) is critical to its research mission and also ensures its standing among the country's top grantees of funding for research, particularly from The National Institutes of Health and The National Science Foundation. Both agencies have expectations about RCR training for undergraduates involved in research. To meet these expectations, undergraduate students engaged in research activities at UAB are required to complete RCR training described below prior to the start of the research experience.

At UAB, RCR training for undergraduates is provided online through six CITI Program modules. The required modules cover the following core topics:

- Introduction to RCR
- Data Management
- Research, Ethics, and Society
- Plagiarism
- Research Misconduct
- Authorship

Non-required modules address topics including research involving human subjects, use of animal subjects in research, and conflict of interest. Supplemental in person training, which reinforces information within the online modules, is strongly encouraged, but not required. Such training may be accomplished via in-class discussions of an undergraduate research-related course or an RCR-related workshop. For more information on RCR training for undergraduates, visit the Office of Undergraduate Research's webpage on RCR.

New Policies Coming Soon

UAB is currently considering two new policies, drafts of which have been submitted for the University community's broad review. As a heads up on what they're about and how they'll affect UAB business, a synopsis of each draft policy appears below.

Electronic Signatures Policy: This new policy is intended to promote efficiency of University business transactions that require approval or authorization by establishing the basis on which electronic signatures are accepted. Federal and state law recognizes that an electronic signature has legal effect and is enforceable. The University encourages the use of electronic signatures, so long as their use meets legal, security, and internal process requirements. This policy will apply to all employees and students.

Event Scheduling Priorities for UAB Facilities Policy: This policy promotes efficient, responsible, and safe use of University facilities by setting forth priorities to be considered when scheduling events and allocating space, especially for requests from individuals or groups from outside UAB. The policy would apply to all University buildings and property, but units with control over specific sites would be responsible for developing procedures to implement this policy in those areas.

The University's policy development process is described in this flowchart. For more information on pol-icies, visit the UAB Policies & Procedures Library, or email any question to policies@uab.edu.

Code of Conduct Corner

Standard of Conduct:
Provide *Quality* Education, Research, Healthcare, and Business Interactions

UAB is committed to providing outstanding services to our students, patients, families, visitors, business partners, colleagues, affiliates, and the community, whether those services are provided through teaching, research, patient care, or business interactions.

In performing duties, UAB community members are expected to:
- Act with high ethical and professional standards of conduct;
- Be honest in performing one's duties, with no exceptions;
- Ask questions and request assistance when information is needed to properly perform one's duties;
- Be personally accountable for one's actions and admit mistakes when they occur;

- Be aware of UAB's obligations towards all stakeholders;
- Conscientiously fulfill obligations towards all stakeholders; and
- Communicate to others ethical standards of conduct and responsibilities through instruction and example.

UAB community members are not to:
- Fabricate information;
- Change or knowingly omit information to misrepresent events, circumstances, results, or outcomes in relevant records; or
- Take credit for another's work or work product as one's own without permission.

For more on the UAB Enterprise Code of Conduct, please visit the University Compliance Office website at http://www.uab.edu/compliance/code.

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