As UAB students, faculty, and staff continue their phased return to campus, we all look forward to the in-person classes, meetings, clinical activities, and campus events we have so missed over the last year. UAB policies and practices serve to reduce COVID-19 risks, and since July 2020, UAB’s COVID-19 Incident Command Committee has actively monitored data associated with their effectiveness so that issues can be swiftly addressed.

In the spring of 2020, UAB administrators gathered the many tools needed to evaluate pandemic trends and threat levels. With these tools in hand, a team comprising 23 members and representing a wide cross-section of University administrative units coalesced to form the COVID-19 Incident Command Committee (ICC).

Meeting at 7:30am three times a week in order to keep current with daily data feeds informing leadership’s decisions, the committee’s charge was handed down from the UAB COVID-19 Incident Command Executive Committee.

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“While the ICC has worked diligently to assess the data on UAB’s experience with COVID-19, it is the thousands of UAB community members doing their part that has made this effort successful.”

— Katie Crenshaw, Chief Risk & Compliance Officer and Chair, COVID-19 Incident Command Committee

UAB’s Implementation of the New NIH Biosketch & Other Support Forms

Our last issue of Compliance 411 focused on the importance of accuracy and consistency in providing information to federal sponsoring agencies and anticipated possible changes to National Institutes of Health (NIH) Biographies and Other Support reporting requirements. On March 12, 2021, NIH released NOT-OD-21-073, which announced new standards for forms to be included in proposals, just-in-time submissions, and Research Performance Progress Reports (RPPRs) submitted on or after May 25, 2021. As communicated to the UAB research community by the Office of the Vice President for Research, UAB is working to implement the new NIH requirements under NOT-OD-21-073.

Biographical Sketches

The NIH Biosketch information page provides the new biosketch form and instructions. UAB faculty and staff may begin using this form immediately. Changes to the biographical sketch form include, but are not limited to, requiring detailed information on scientific appointments in reverse chronological order in Section B.

Beginning May 25, 2021, it will be the University’s policy to require use of the new NIH biographical sketch.

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www.uab.edu/compliance | www.uab.edu/policies
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New Biosketch & Other Support Requirements, cont. from page 1

Other Support

UAB will continue to use the UAB Other Support Template until May 3, 2021. Effective May 3rd, UAB faculty and staff may use either the UAB OS template or the new NIH format page through May 24, 2021. Changes to the OS form include, but are not limited to:

- Reorganization of the format page to separate funded projects from in-kind support (e.g., outside support for lab personnel);
- Requirement that senior/key personnel sign the OS page attesting to the accuracy of information submitted; and
- Requirement that supporting documentation must be attached to the format page where Other Support includes foreign activities and resources, and must include copies of translated contracts, grants and/or other related agreements specific to foreign appointments and/or employment with a foreign institution.

Beginning May 25, 2021, it will be the University’s policy to require use of the new NIH OS format page.

While the new NIH Other Support form may appear more simplistic than the current UAB template, the same transparency requirements apply and elevated scrutiny by NIH continues. The new form requires the same information with the additional new requirements for supporting documentation and faculty attestation/signature. Only the format has changed.

The Office of Sponsored Programs is working with the Office of Compliance & Risk Assurance to update the Guidance document on the Transparency in Research webpage.

Over the next few weeks, Research Administration will be announcing dates for Town Hall sessions to provide guidance and answer questions related to the new NIH Biosketch form and Other Support form to support the UAB research community in meeting our sponsors’ requirements for complete transparency in disclosure of all research activities, both foreign and domestic.

Here are some examples of NIH enforcement response in instances of non-compliance with documentation transparency requirements at UAB:

An investigator did not ensure that project start/end date information included in a biographical sketch submitted with a grant transfer application was consistent with the notice of award, resulting in the funding agency requiring numerous proposals to be withdrawn.

An investigator did not ensure all appointments, specifically adjunct faculty positions at other institutions, were listed in Other Support pages submitted to a funding agency. This resulted in multiple Other Support pages requiring correction to disclose all required information to the funding agency.

Investigators omitted financial conflict of interest (FCOI) disclosures in two publications in which they were listed as co-authors. A federal sponsor noted this omission and required a retrospective institutional review for bias and update regarding corrective actions taken.

UAB supervisors whose job includes management of state funds in certain capacities or who meet a salary threshold of $81,000 are required to complete an annual Statement of Economic Interests (SOEI) form by April 30, 2021 for the preceding calendar year. Individuals to whom this mandatory filing applies received an email from the UAB Chief Human Resources Officer on February 18, 2021. For more information, visit the Alabama Ethics Commission SOEI webpage.

Alabama Ethics Disclosure Deadline

April 30

April 2021
ComplianceBridge Policy Management Platform Coming in 2021

In partnership with stakeholders from University policy-making units, the Office of Compliance & Risk Assurance is working towards implementation of ComplianceBridge, the university’s new policy development and management platform, with full implementation anticipated this year. You may find the transitional library at www.uab.edu/policies. A complete list of policies and procedures can be accessed by selecting “Find by Title” on the “Search Library” drop-down menu. While full-text search is currently disabled on the transitional site, using CTRL+F while on the title index page will produce a keyword search of all titles. If you can’t find a policy or procedure, please contact policies@uab.edu. Your patience is appreciated while the new system is under construction.

UAB Enterprise Conflict of Interest and Conflict of Commitment Policy

A committee comprising representatives from academic and administrative offices across the University and UAB Health System has revised the UAB Enterprise Conflict of Interest and Conflict of Commitment Policy, effective January 1, 2021, to address shifts in in expectations for public transparency, research regulatory requirements, approaches institutions take to identify and manage conflicts of interest and commitment, and requests from internal stakeholders for greater clarity in requirements and processes. The revision was approved at the System level per the University of Alabama System Board of Trustees’ Board Rule 108.

Academic Integrity Code

Having been through the several stages of the University’s Policy Development Process, UAB’s new Academic Integrity Code will soon be presented to the UA System Office for final approval. At this time, the draft policy has been reviewed by faculty, student, and administration representatives, including the President’s Risk Cabinet, and endorsed by the Faculty Senate.

All students are expected to be familiar with and abide by the Academic Integrity Code, which supports UAB’s academic mission and promotes integrity, honor, and professionalism in conduct appropriate to a community of scholars. Therefore, training opportunities will be made available for students and faculty to familiarize themselves with the requirements and expectations of the policy.

Questions about the Academic Integrity Code should be directed to the Office of the Vice Provost for Enrollment Management at provost@uab.edu.

For general information on the University-wide policy Development Process, please view this pdf. Please direct questions and comments to policies@uab.edu.

Compliance CHALLENGE

Read the hypothetical scenario below. Click on an answer A-D by June 15, 2021 to enter a drawing for one of two $10.00 Amazon gift certificates. Only those with addresses ending in uab.edu or uabmc.edu qualify.

Dr. Smith has a Research Performance Progress Report (RPPR) due to NIH on June 15, 2021. She was recently awarded a new NIH R01 grant. As a result, Dr. Smith must update her Other Support document to ensure it includes all required information. How can Dr. Smith and her administrator help ensure the Other Support document includes all information required by NIH and help ensure the information is consistent with UAB records?

A. Reference Dr. Smith’s projects listed in the University Compliance Projects by Responsible Person e-Report or the Other Support Reconciliation e-Report.

B. Use the Visiting Scholars and Scientists Funding Sources report to identify individuals working in her lab on a J-1 visa.

C. Visit UAB’s Transparency in Research website for guidance on UAB information sources.

D. All of the above.
With the increased ability to collaborate globally, UAB requires Data Use Agreements (DUAs) to ensure safeguards are in place to protect data shared with other parties. Here’s why DUAs are required and the process by which they are initiated at UAB.

A DUA is a contract that governs the exchange of specific data between two parties. Often, investigators seek to share data with collaborators working outside their institution. But without proper safeguards in place, data sharing can potentially violate regulations and have considerable ramifications for both UAB and individual investigators. Data should not be shared before considering whether a DUA should be in place.

A DUA is most vital when seeking to share restricted or non-public data. When the data is restricted or non-public, a DUA is used to govern issues including, but not limited to:

1. Privacy rights;
2. The parties permitted to use the data;
3. The authorized use of the data;
4. The legal obligations required to safeguard data; and
5. Any potential liabilities resulting from the unauthorized use of the data.

To initiate a DUA at UAB, investigators must submit the proper information to UAB’s Office of Sponsored Programs beginning with the completion of a UAB Data Use Agreement Checklist. The UAB Data Use Agreement Checklist identifies the information and documentation required for the initiation of a DUA.

The Office of Research website provides valuable information regarding DUAs and should be consulted when assessing the need for a DUA and before making a DUA submission to OSP.
Investigators and study teams should remember to maintain compliant records in ClinicalTrials.gov by completing the annual updates and reporting results prior to the posted due dates. Investigators and study teams can find their posted due date on the “Record Summary” page. Late reporting of results is tracked, and civil monetary penalties could be assessed based on the number of days the reporting is late.

FDA guidance from August 2020 addresses civil monetary penalties the FDA could pursue in cases of non-compliance against sponsors, responsible parties, and submitters of certain applications and submissions. Moreover, the guidance details the series of actions the FDA can take to allow the responsible party to remedy non-compliance before imposition of monetary penalties is considered.

If a sponsor fails to comply with the requirements, the FDA will send a Preliminary Notice of Noncompliance (Pre-Notice) as a first step to rectify the noncompliance. Failure to comply within 30 days may result in further regulatory action, including the issuance of a Notice of Noncompliance with civil monetary penalties, injunction, and/or criminal prosecution. Penalties can be costly. Initial fines are up to $10,000 per proceeding, which may address several violations at once. However, if violations are not corrected within 30 days following notification, the FDA may impose additional fines of up to $10,000 for each day that the violation continues. Additionally, late reporting of results could impact the assignment of future awards.

For any questions or assistance with all ClinicalTrials.gov-related issues, please contact Denise McKenzie at dhmckenzie@uabmc.edu.

Brief Form Optimizes Small-Business Proposal Workflow

To optimize efficiency in the processing of Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) proposal submissions, Principal Investigators must submit a Notification of Intent to Submit an SBIR/STTR Grant Application with a Small Business Concern form at least 30 days prior to the proposal’s submission due date. The form asks for basic information about the proposed award and should take no more than 10 minutes to complete.

Submission of this brief e-form provides UAB central administrative units advanced notice of an anticipated proposal, thus allowing important information to be gathered regarding a proposed Small Business Concern (SBC) partner and helping to ensure appropriate UAB intellectual property agreements are timely in place. This notice also allows for early assessment/management of other considerations, including any possible conflicts of interest or commitment. The working draft proposal, along with other required documents, remain due five business days prior to the anticipated proposal submission date.

The next NIH SBIR/STTR deadline is September 8, 2021. PIs anticipating partnering on a submission for this deadline should complete the 30-day Notification of Intent to Submit for by August 9, 2021.
UAB faculty and staff owe their primary professional allegiance to UAB and its mission to excel in the highest levels of education, patient care, research, and scholarship. And with federal research sponsors’ increasing scrutiny on transparency and diligence in disclosure of all funding sources and activities of research key personnel, this pillar of the UAB Enterprise Code of Conduct is more important than ever in order to promote and maintain public trust.

UAB community members have an obligation to be objective and impartial in making decisions on behalf of UAB. External professional activities, private financial interests, or the receipt of benefits from third parties can cause an actual or perceived conflict between UAB’s interests and an individual’s private interests. UAB community members are expected to:

- Accept benefits, awards, and prizes from external entities only in accordance with established UAB policies and standards;
- Disclose relationships with third parties, such as consulting, board membership, or professional services, in accordance with UAB’s process to ensure objective judgment in purchasing, research, and other UAB business and to identify any potential or actual conflicts of interest;
- Adhere to any management plans created to manage conflicts of interest; and
- Ensure one’s personal relationships do not interfere with objective judgment in decisions affecting UAB employment or academic progress of any UAB community member.

Congratulations to Compliance Challenge Winners!

Winners from the Dec. 2020 Compliance Challenge are the School of Public Health’s Laura Wilson & the School of Medicine’s Becky Warnix. By participating, they each won a drawing for a $10.00 Amazon gift certificate. To participate in this issue’s Compliance Challenge, please see page 3.

Becky says, “I like to read the Compliance newsletter to stay informed on the latest news and updates.” Laura reads Compliance 411 “to be aware of any important developments and to maintain compliance with UAB and the Alabama Code of Ethics.”

Laura Wilson, Program Coordinator II for the Deep South Center for Occupational Health & Safety, shows off her winning ways by masking for everyone’s safety.