In response to the COVID-19 pandemic, federal and state governments have allocated over one trillion dollars in relief funding. Historically, past crises have driven government enforcement agencies to more closely scrutinize for false claims, elevating the importance of compliance with the False Claims Act (FCA). A March 19, 2020 National Law Review article highlights the need for organizations to "Guard against false claims as massive government spending rolls out to combat COVID-19."

Although, generally speaking, inadvertent mistakes are not prosecuted, the FCA allows the government to seek treble damages and severe financial penalties against persons submitting false claims to the government. Also, most states have their own false claims laws and regulations that apply to state and local government funding.

### UAB EH&S Issues COVID-19 Containment Research Manual

On March 31, 2020, The UAB Department of Environmental Health and Safety issued [UAB EH&S COVID-19 Containment Guidance for Researchers](#). CDC and NIH guidelines clearly define research with the SARS-CoV-2 virus as Biosafety Level 3 (BSL-3). Research involving COVID-19+ (SARS-CoV-2 infected) patient samples may be conducted in Biosafety Level 2 laboratories that can meet the enhanced containment criteria described in the research manual as “BSL2+,” except for studies involving virus isolation or propagation. All research isolating and...
University Compliance & Risk Assurance: A Conversation with Teresa Bragg

You have mentioned that one of your proudest achievements at UAB was early on when the UAB Enterprise Code of Conduct was developed and disseminated. What makes it so important in your view?

The UAB Enterprise Code of Conduct is the overarching policy that unifies the University and UAB Medicine and sets the standards which all other policies and procedures must meet or exceed. It stems from the vision and mission of the organization and describes what it looks like to act out of UAB’s values of integrity, respect, and collaboration. UAB’s Code of Conduct is even used as a model for the UA System and other sister institutions.

What is the philosophy of the Office of Compliance & Risk Assurance when it comes to ensuring compliance is at the forefront of the UAB operations?

A solid compliance program is built on increasing awareness of compliance risks and responsibilities and then engaging leadership in addressing them. UAB’s model for this foundation is the risk assessment and mitigation process and the establishment of Executive Risk Oversight Committees (EROCs) for each school and the college. Because EROC committee members partner directly with our team’s compliance officers to identify risks particular to departments and schools and the best ways for those entities to reduce those risks, the EROCs exemplify the importance of having the right people in the right roles. In support of all this, educating and training on policies and procedures must be must be continuous along with the use of technology to make compliance easy.

Looking back, how has the University’s approach to risk matured over the years, and has that affected its ability to address risks?

The University Risk Intelligence program continues to evolve. During my tenure at UAB, we nurtured it beyond

Continued on page 8, see “Teresa Bragg”

Sponsor Guidance for Researchers During COVID-19 Crisis

Guidance from agencies sponsoring research continues to evolve as the impacts of the COVID-19 crisis are felt by grantee institutions and research teams. Sponsor policies and practices have been revised to keep essential research going safely while also accommodating limited business models.

For an up-to-date compendium of UAB-specific guidance and requirements, visit Research Administration’s website on Guidance for Researchers During the COVID-19 Crisis. Additionally, to help investigators and their staff make sense of the multitude of new requirements and suggested practices, the Council on Government Relations has gathered and made available relevant information, the links to which are listed here:

- FAQs
- Agency and institutional responses
- Federal agency guidance matrix
- NIH FAQ Addendum #1 with new FAQs
- Costing FAQ Addendum #2

Resources for Preparing Other Support Pages

As federal funding agencies increase scrutiny of documentation submitted in support of sponsored projects, UAB is compiling guidance that will assist our research community in preparing and reviewing Other Support pages. UAB databases that provide sources of information relevant to preparing and/or reviewing Other Support include but are not limited to OSP/IRAP eReports, Oracle, External Activity reports, and the UAB Profiles System.

It is critical to satisfying regulatory and UAB policy requirements that UAB investigators reconcile data from these various sources to ensure the information they provide at just-in-time phases and in progress reports about resources available for support of their research endeavors is complete and accurate. Investigators can access the new UAB Other Support Template and accompanying instructions on the Office of Research’s webpage on Transparency in Research. Additional guidance is being coordinated across several units within Research Administration and Compliance & Risk Assurance for integrating datasets consistently across these resources as well as presenting them clearly and concisely.
The Office of Compliance & Risk Assurance caught up with Dr. Gopalakrishnan by phone shortly after UAB instituted a limited business model due to COVID-19. During the conversation, it became clear that, despite the pandemic, HIIE and its mission to foster UAB entrepreneurship is still full speed ahead.

**OC&RA:** What business philosophy drives your team’s efforts to grow innovation, entrepreneurship, and commercialization for UAB and its acclaimed field of talent?

**Dr. Gopalakrishnan:** For us, it’s all about communication. We want the internal community of UAB researchers to know who we are, what resources we offer, and the wide spectrum of inventions that can be monetized or moved into the market to create public good. For external partners seeking to engage with UAB, we want to educate about our process and timelines.

**OC&RA:** What resources does HIIE offer that foster entrepreneurship for UAB faculty and students?

**Dr. Gopalakrishnan:** To highlight just a few: We have partnered with the Collat School of Business to help potential start-ups with business plan creation. Our team is active on the UAB Entrepreneurial Development Committee (EDC) and Entrepreneurial Oversight Committee (EOC), working groups which have been assembled to streamline the process of conflict management. And students from any discipline or year of study can navigate the entrepreneurial process and connect with experts from the community through our Anvil Student Startup Bootcamp.

**OC&RA:** In addition to conveying the importance of the initial step of disclosing IP to HIIE, what would you like to tell inventors who are in the nascent stages of entrepreneurship?

**Dr. Gopalakrishnan:** We’ve updated our internal review processes to facilitate quicker patent decisions. Our office now provides a commercialization report for each new disclosure. And our marketing efforts are now more robust than ever. We are engaged with the community and can connect researchers with external resources, including talent, infrastructure, and sources of capital.

**OC&RA:** What happens after an IP disclosure is received? What are the factors that determine if IP is patentable, licensable or if a start-up company should be formed? How long does it take to make these initial determinations? If someone has questions about any of these processes who should they contact?

**Dr. Gopalakrishnan:** Once an invention is disclosed to our office, we develop a commercialization report that is shared with the researcher within one month. We use the report findings and feedback from the researcher in determining the path to commercialization, including whether or not to patent the invention.

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**Continued on page 4, see “Gopalakrishnan”**

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“At UAB, intellectual property disclosure initiates processes that help catalyze innovative research to impact.”

— Karthik Gopalakrishnan, PhD
The UAB Research Foundation (UABRF) welcomes your disclosures and looks forward to working with you.

The Intellectual Property Disclosure Form is used to disclose any intellectual property (i.e., a new process, composition of matter, device, software, analytical tool or new use for a known compound) developed in whole or in part by employees and students of UAB to UABRF. Once a completed IPD is received, a licensing professional from UABRF will be in touch to begin the evaluation of your invention, and members of the UABRF staff will review and evaluate the intellectual property to determine if it should be protected by patent or copyright and whether it can be marketed and/or licensed to industry for further development and commercialization. For assistance, contact innovation@uab.edu or 205-934-9911. Submit completed forms by email to innovation@uab.edu.

Throughout the process, we are here for any questions they may have.

OC&RA: The challenging business environment caused by the pandemic can be seen as a great opportunity to create new ways to deliver value and open new markets. Has HIIE seen any recent UAB innovations that specifically address pandemic-related health issues?

Dr. Gopalakrishnan: Face-to-face meetings are currently on hold while many of us across the country are working from home. But this time presents a unique opportunity to explore new ways to connect, not only within our current ecosystem but also by expanding our network. Our team is harnessing this time away from the office to experiment with new channels and ways to market our available technologies to potential licensees. We’re also taking another look at our portfolio to see what inventions might hold relevance in light of current events.

A great example comes from the UAB Health System: a hand-sanitizing system designed to alert those entering or exiting patient areas without cleaning their hands. This technology has tremendous potential impact for healthcare facilities even before recent events. It’s currently being validated in the health system, and we’ve added it to our short list for marketing to potential licensees.

One reason we love this example is that it’s not a research tool or software – inventions you might traditionally think about when discussing Intellectual Property – but it could greatly impact the community very soon.

State Ethics Commission Statement of Economic Interests Due April 30

UAB employees who meet certain criteria have a legal duty to file a Statement of Economic Interest (SEI). UAB employees who meet these criteria received email notification from the UAB Office of Human Resources on Wednesday, March 9. Please note that the SEI requirement does not replace any UAB requirement to obtain advance approval of external activities or disclose financial interests under UAB conflict of interest policies.

The form may be completed online at https://ethics-form.alabama.gov/default.aspx and must be received by the Alabama Ethics Commission no later than April 30, 2020. More information about the Statement of Economic Interests is available here. You may also see the Human Resources Records Administration webpage for more information.

Responsibility for compliance with the Ethics Act, including the duty to file the Statement of Economic Interests, rests with the employee. Employees who are required to file a Statement of Economic Interests with the Ethics Commission but fail to do so timely may be fined $10.00 per day, not to exceed $1,000.00, or be charged with a Class A misdemeanor for intentional failure to file (see Alabama Code, Section 36-25-14(d) & (e)).
Timely posting of clinical trial summary results on ClinicalTrials.gov ensures compliance with Federal and State law and funding agency regulations concerning the public availability of clinical trial data on ClinicalTrials.gov. UAB researchers are responsible for creating and maintaining records in ClinicalTrials.gov to meet expectations of the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the International Committee of Medical Journal Editors (ICMJE), and Centers for Medicare & Medicaid Services (CMS).

Congratulations are in order for all UAB clinical trial study teams who reported their work in a timely fashion to achieve a 100% compliance score for the first time since the statutory requirements for registration and reporting results were established in September 2007. This achievement is especially significant because, in January 2017, regulatory requirements were expanded to include a penalty phase for non-compliance. Kudos also to UAB’s CT.gov Team Denise McKenzie, Dorothy Shaw, and Hina Amanullah of UAB’s Center for Clinical and Translational Science!

- As of March 6, 2020, UAB has a total of 894 total studies registered in the ClinicalTrials.gov Protocol Registration and Results System; 378 are identified as “Active.”
- Full protocols are required to be uploaded for studies required to report results. Human Subject Protocols (HSPs) are internal UAB documents and, as such, do not meet the full-protocol disclosure requirement.
- There has been recent concern that posting required results in CT.gov before the study appears in a journal would preclude the manuscript from being accepted by the journal. While the ICMJE may consider posting of more detailed descriptions of trial results differently, they do not consider results data posted in the tabular format required by CT.gov to be a prior publication.

If you have questions, please contact Denise McKenzie at dmckenz@uab.edu. For more information, please visit UAB’s ClinicalTrials.gov Registration webpage.

### Summary Results Posted for Due Clinical Trials Subject to FDAAA, % Compliance by University*

![Graph showing % Compliance by University](image)

*From “Clinical trial transparency at U.S. universities” by Universities Allied for Essential Medicines and TranspariMED.

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**Compliance CHALLENGE**

Read the hypothetical scenario below, and click on an answer A-D to enter a drawing for one of two $10.00 Amazon gift certificates to be held June 15, 2020. Only those with addresses ending in uab.edu or uabmc.edu qualify.

Prakesh and Matt, both COVID-19-related essential research lab personnel, and their coworkers have been directed by the Primary Investigator to limit the number of people present in the lab to two to reduce risk of transmission of COVID-19 from one person to another while ensuring no one works alone, per UAB’s Guidance for Mentored Research under Limited Business Operations. The PI and her team devised a schedule of staggered pairs and a workstation layout that supports social distancing of at least six feet at all times. Prakesh and Matt have been designated as a pair but have found it impossible to respect the six-foot rule because a piece of shared lab equipment is less than six feet away from both of their workspaces. They are concerned and want to ensure each other’s safety for the duration of this work arrangement. What should they do?

A. Ignore the six-foot rule since they both wear gloves and sanitize their work surfaces upon arriving and leaving.
B. Conduct their work alone at separate times.
C. Ignore the rule because COVID-19 is dangerous only to those over 65.
D. Inform the PI and request rearrangement of workspace and equipment in support of the six-foot rule.
Feature-rich LabArchives® Reduces Lab Notebook Security Risks

To reduce risks of theft, hacking, unauthorized copying, and inconsistent research data management practices, UAB has recently transitioned to a unified electronic laboratory notebook (ELN) system called LabArchives®. Appropriate use of LabArchives® also addresses requirements related to:

- Federal policies concerning public access;
- HIPAA, FERPA, and FISMA regulations;
- Export control;
- University of Alabama System Board of Trustees Rule 105, Ownership and Preservation of Records and Files;
- Scientific integrity; and
- Grantor data management requirements.

LabArchives® is a secure, intuitive, cloud-based ELN system that provides a flexible platform that can be customized to different lab workflows while maintaining consistency in compliance with funding agencies’ data management requirements. Features include:

- Access management through personnel assignment to certain notebooks and/or notebook pages;
- Connection of all data to observations and notes;
- Ability to import and access digital experimental data captured from original lab machines, whether produced by hardware or software;
- Ability to upload videos and images directly to notebooks while conducting experiments;
- Audit control that tracks and stores revisions of all entries;
- Prohibiting of data deletion, thus protecting both research integrity and intellectual property;
- Publishing and sharing of notebooks with individuals and the public;
- Cross-platform functionality, including iOS and Android devices*;
- Integration with Shibboleth authentication and BOX; and
- Multiple functionalities to enhance research, including chemical inventory and freezer box inventory tools.

In addition to UAB, there are currently 90 research enterprise licensees including MIT, Cornell, Columbia, Brown, Mount Sinai Medical Center, University of Massachusetts Medical Center, Duke, and the Universities of Pennsylvania, Pittsburgh, Michigan, and Wisconsin.

LabArchives partner Amazon Cloud Services monitors cloud servers 24/7; provides visual access to UAB researchers only; encrypts data in transit, at rest, and in back-up; maintains different, redundant back-up locations; and ensures all UAB data remains only in the U.S.

LabArchives® is available at no cost to users or departments, and there is no limit on data storage space. Units will perform annual efficacy evaluations in order to modify, if necessary, strategies for the optimal use of LabArchives®.

For more information on using LabArchives in your lab, visit UAB’s LabArchives® website, or contact support@labarchives.com, Dr. Kent Keyser at ktkeyser@uab.edu, or Kim Wilcox at wilcoxk@uab.edu.

*LabArchives works with the following browsers: Chrome, Edge, Firefox, and Safari. It does NOT support Internet Explorer.

Essential Research Activities During COVID-19: Definition, Approvals, and Personnel Requirements

The Office of the Vice President for Research has provided guidance about essential research during this time, including how essential research is being defined, who needs to approve exceptions, and what personnel are allowable on essential research projects. As this guidance necessarily evolves with changing requirements, especially in the areas of safety and sponsored-project compliance, Research Administration’s webpages on essential research are updated regularly. To stay informed of critical changes to operations as a result of the COVID-19 pandemic, visit the UAB Office of Research Guidance’s webpage.
See something? Say something.

UAB’s Violence Prevention and Response Policy supports UAB’s commitment to a culture of trust, integrity, and accountability by maintaining an environment of open dialogue. UAB employees, students, and volunteers do the institution a service by raising constructive questions or concerns about wrongful conduct on campus and by collaborating with leadership to address them.

Did you know that . . .
- UAB prohibits retaliation against those who report wrongful conduct in good faith?
- A Secret Service study found that in 75% of cases of school violence, the perpetrator expressed intent to harm before inflicting the harm?
- University employees are required by Alabama law to report known or suspected child abuse? (See UAB’s Policy on the Protection of Children on UAB Premises and in UAB Sponsored Activities.)

Remaining silent about wrongful conduct takes away an opportunity for the University to assess and respond to an issue. Avenues for reporting include:
- 911 or UAB Police (934-3535) for imminent threat or danger,
- UAB’s Behavioral Threat Assessment & Management Team’s online form for reporting a concern for non-emergency behaviors of concern,
- Department/unit leadership, supervisors, or managers,
- Office of Compliance & Risk Assurance (205-996-6540)
- HR Employee Relations (205-934-4458), or
- UAB Ethics Hotline (866-362-9476, 24 hrs./day, 7 days/week)

Reporting wrongful conduct in good faith, and the prohibition against retaliation for doing so, are also supported by UAB’s Duty to Report and Non-Retaliation and Title IX Sexual Violence and Sexual Misconduct policies.

You can make a difference.

Code of Conduct Corner

Standard of Conduct: Provide a Safe Environment

Now more than ever, UAB community members have a shared responsibility to ensure a safe, secure, and healthy environment for all UAB students, patients, faculty, staff, volunteers, and visitors. UAB community members are expected to:

- Promote personal safety and follow safe workplace practices, including participating in applicable education sessions, using appropriate personal safety equipment, and reporting accidents, injuries, and unsafe situations;
- Maintain security, including securing UAB assets;
- Report suspicious activities; and
- Protect the environment, including carefully handling hazardous waste and other potentially harmful agents, materials, or conditions. (See especially the article on page 1 about EH&S’ new UAB COVID-19 Containment Guidance for Researchers.)

Click here for examples of how UAB’s commitment to safety may apply to your daily activities.

Don’t forget to participate in this issue’s Compliance Challenge on page 5 to enter a drawing for a $10.00 Amazon gift certificate!
Increased False Claims Enforcement, continued from page 1

Here are steps to reduce risk of violating FCA:

- Stay informed about regulatory requirements for managing sponsored research during extraordinary circumstances;
- Review and understand all conditions of payment before submitting claims;
- Train and educate employees about the risks of non-compliance;
- Maintain strong compliance programs;
- Prepare and maintain detailed records of transactions; and
- Have a plan to promptly respond to reports of potential fraud, waste, and abuse.

For more information, see the article on page 2 on guidance from the Council on Government Relations on federal agency requirements during COVID-19’s impact on proposals and awards.

UAB EH&S Issues COVID-19 Containment Research Manual, continued from page 1

propagating the virus (including the culture of potentially-infected cells) must be performed in the UAB SEBLAB, which houses state-of-the-art BSL-3 laboratories as well as animal BSL-3 laboratories.

The Principal Investigator is ultimately responsible for providing training and ensuring staff and students are proficient in the practices and procedures required of them. This containment guidance manual is provided to assist PIs in the development of a laboratory-specific biosafety manual with instructions to safely handle and manipulate COVID-19+ patient samples under enhanced BSL-2 laboratory conditions. Some of the “enhanced” requirements include:

- doors remain locked to restrict access to authorized personnel only
- laboratories are verified to maintain negative pressure, compared to public corridors
- all work with potentially-infectious materials is conducted inside a biosafety cabinet or other primary containment device
- two sets of gloves are used for working with infectious materials in the biosafety cabinet
- all potentially contaminated materials are disinfected prior to disposal

For additional information concerning this guidance, please contact a biosafety representative at 934-7488, or biosafety@uab.edu.

Teresa Bragg, continued from page 2

involvement of just a handful of organizational leaders to a more formalized whole organization approach, with leadership, faculty, staff, and students working toward a shared understanding of risks and responsibility to see they are addressed. And with increasing emphasis on research, innovation, and entrepreneurship, it will continue to be important for UAB to consider risks right alongside the benefits of pursuing big opportunities.

What are some examples of when you saw UAB demonstrate a commitment to shared values of integrity, respect, and collaboration?

Broad input from all areas of campus on institutional policy decisions has been strong and consistent for several years now; this is vital to avoiding operational silos and to applying policies consistently throughout all areas of a large institution of higher education -- especially one where sponsored research funding is measured in the hundreds of millions of dollars.

Collaboration across units to develop process improvements and internal controls has also been strengthened. I’ve also seen departments demonstrate integrity and strength by addressing situations where non-compliance has been identified, especially by implementing corrective action plans that required changing their practices and demonstrating that their implementation was effective. I found and appreciated during my time at UAB that leadership welcomes and is willing to address feedback in the spirit of meeting highest quality standards.