

ROC Meeting Notes
Wednesday, January 19, 2022
9:00 – 10:00 AM

Andy Byrd, Office of Commercialization and Industry Collaboration

- Update on MTA Process – Since Reggie Taylor has retired, we have updated our point of contact information on the OCIC website: <https://www.southalabama.edu/departments/research/ocic/>, as well as some procedural updates on how we route material transfer agreements to make sure the researchers are getting their reviews done in a timely manner and getting materials that they should receive. All of the material transfer agreement (MTA) forms have been updated, with the new email address: techtransfer@southalabama.edu, with additional information, including a new procedure for MTAs.

The main reason for the MTA is to manage the liability of the entity that is providing materials to another entity so, it is important to have the proper compliance review and have the proper parties identified. In order to make it easier to navigate, we have added a Material Transfer Agreement icon to the OCIC page. When you click on the icon for MTA, you will see some new drop downs, the first one helps explain the importance of the MTA process. The major update is the absence of Reggie Taylor's email address, if you send anything to his email address, it will go directly to my archive account where I can catch the emails. You should receive an automatic response letting you know of the new departmental address for confidentiality agreements and MTAs.

There are also new tabs for MTA Guidelines and the review procedure and timeline, which gives a little bit of transparency to what we do and a realistic expectation of our turnaround time, which is usually 2 business days if it is a standard MTA without any export control issues and no government select agent issues. If it is the universal biological MTA, we can turn those around quicker. If it is from another university or another outside entity and it is their MTA that they want us to use, then we have to review and negotiate the agreement, but that typically takes about a week.

Our MTA guidelines were not previously available on the website, but it contains a nice bit of information, including the University's guidelines as well as the process as a whole, whether it is an incoming or outgoing MTA, what the compliance review looks like, what we are looking for, when should you need to be talking with the Research Compliance office, et al. There are also some links and, of course, the two sections everyone uses: sending and receiving money material transfer agreements.

For those who are not familiar with our process, we have all of the different types of MTA forms available on our site, which includes a MTA pre-review questionnaire. It does not matter if we are sending or receiving materials, if you have a researcher that needs to send some materials outside of the University, or you have a researcher that is receiving from another entity, we require this MTA pre-review questionnaire; and the purpose of this is to initiate the review process of the material and essentially we can initiate the export control process. OCIC is the landing platform for export control screening, so we will look at who is the recipient, who is going to be receiving this material outside the University, and we will run what is called a restricted party screening, which is the best way to check and verify that the receiving party has not been restricted by Federal law from receiving. If there is a red flag, we will bring in Dusty's office for research compliance and they will handle it from there. OCIC does that initial restricted party screening, which helps initiate that process that helps us verify the receiving party's information, or the sending party, if it is incoming and then we can look and see if the materials themselves or the government select agents or the materials themselves are subject to any sort of special considerations.

The pre-review questionnaire is not always sent prior to receiving an MTA request, this will be kicked back to the sender. We would like to go ahead and receive the MTA, especially if they are from another research organization or private party, we can go ahead and review those to see if there are any terms that need to be negotiated. But, ultimately, we do require the pre-review questionnaire prior to we can complete the review and fully process the MTA. If we are receiving or sending materials, the University

is a subscriber to the NIH Uniform Biological Material Transfer Agreement (UBMTA), which is pre-negotiated, pre-agreed upon standard language for biological materials. If you have a PI where a UBMTA is appropriate, we have an UBMTA implementing letter that needs to be filled out and signed – no separate MTA form is required. When we are sending material courses a pre review questionnaire, the UBMTA if it is outgoing material. If we are sending it not to another university, but a private entity, we have a commercial MTA for biological materials, which has some different language and worded differently for restrictions on use by commercial entities.

We also do transfer materials that are non-biological in nature, such as chemicals, carbon fiber prototypes.

If you have any questions, please contact me. I will be monitoring the Tech Transfer email account now and for the foreseeable future, or email me directly.

Angela Jordan, Office of Research Communications, Development, & Learning

- Limited Submissions Update – What is a limited submission? A limited submission is when an external sponsor has a limit on the number of applications that an institution can submit and is often one, sometimes up to three submissions. We need to control the process because we want to make sure that we are not submitting more than the restricted number of applications. For example, if you had a competition say from NSF, and they allowed only one applicant per institution, and we had more than one researcher who wanted to apply for it and did not let Sponsored Projects know. They might just both submit and, in that case, the sponsor can reject both applications. Different sponsors have different rules for this – sometimes they can reject all applications submitted, or they will only select the first one submitted. If the second one to submit was the actual one that we intended to submit, but the other got in first, then we would not be submitting the application that was intended.

Why would you have a limited submission? This is a way for the sponsor to help ensure that they get a higher quality of applicant so only the best application from your institution can be submitted, the way many that many institutions handle this is through a limited submission process, an internal competition.

Limited Submission process – There are generally two to four steps, depending on how it goes. Step 1: Whenever a PI or research administrator becomes aware that they are planning to submit to a limited competition – this is noted in the funding opportunity announcement of how many can apply from an institution, they will need to let me know via phone or email, that there is a limited submission competition. 2. We will send out emails, usually department chairs and research teams, asking them to solicit their faculty to see if there is additional interest in this competition, can you please ask if anyone else is wanting to submit. Once it is confirmed that there is not anyone else applying, we can go ahead and “award” the nomination to that person. 3. If there are more people who want to apply, than we have available nominations – only one applicant per institution, then we initiate an internal competition that is done via InfoReady, then send out the notices. It is often a quick turnaround because sometimes we don’t find out about the competition until someone is basically preparing their application, becoming an afterthought. Sometimes the sponsors will announce these opportunities and don’t give much lead time, maybe six or eight weeks. Once we have all of the applications, we review them and then, once the nominee has been decided on, we will then issue an institutional nomination memo to the recipient. This does not have to be submitted with their proposal, but it will need to be uploaded into the Cayuse file. You can also find this process on the Research Communications, Development and Learning website: <https://www.southalabama.edu/departments/research/rdl/limited-submissions/>, where you will also find a calendar of limited submission competitions, there are some sponsors that run annually.

Dusty Layton, Research Compliance and Assurance

- Research Compliance and Clinical Trials: Staffing Updates – Staffing updates were announced which have an impact on both administrative support and management in the clinical trials operations arena. Stefanie White, who served in the position of Associate Director, Research Quality and Improvement for

the Office of Research Compliance, has assumed the role as the Interim Director for the USA Health Clinical Trials Office. Stefanie will continue to work in Research Compliance a half a day a week in the interim period. Suzanne Robbins, IRB Compliance Specialist, retired in December. We have made a new hire to fulfill her role in the IRB office, Ms. Caroline Gratton, who will start next Monday, January 24th. Ms. Gratton comes to the University with previous experience with both IRB as well as facilitating and working clinical trial research sites. As mentioned previously, Reggie, who handled the clinical trial negotiations and agreements, has retired from the University. Ben Kearns in Sponsored Projects Administration, will now be assuming these responsibilities.

- Conflict of Interest 2022 Annual Campaign – The Conflict of Interest Annual Campaigns does not necessarily affect all of you, although some in administrative management positions will be affected by the requirements to complete an annual disclosure. Everyone should be aware of and be familiar with the process. Our electronic platform, COI Risk Manager, is used to submit and review conflict of interest disclosures, which are required annually by all USA faculty members, managers and, again, some individuals in administrative positions. We are approaching our 2nd annual campaign, and we, Chris Hansen in the Office of Compliance, and myself, will be sending out a notice to give everyone a heads up that COI Risk Manager will be sending an email notification to remind everyone, which will give them instructions to prompt to log in to the portal and complete their disclosure. The deadline for completing the disclosure is set for March 11th so, there will be plenty of time to complete that process for both the participant who is required to disclose, and the reviewer who was responsible for logging in a documenting the review. Chris Hansen has really taken the lead on this, I have helped facilitate in some capacities, though creating instructional videos for both the participant and the reviewer. We are hoping that these new resources/tools will help aid in this process of disclosure and evaluation. Even though not everyone here is responsible for completing the process of disclosing COI annually, many of you are involved in completing the grant submission form for PHS funded proposals and proposals that certain non-PHS organizations comply with the PHS conflict of interest regulations. This requires listing names of those key research personnel on the COI Certification Sheet. It is the Compliance office responsibility to ensure that those individuals have disclosure forms on file.

Since we now have a process in place where faculty are required to annually disclose, we are ensured that the institution is compliant with the COI regulations; however, there will periodically be individuals listed on the COI Certification Sheet that is non-faculty. It is our office responsibility to ensure that we contact those individuals, create a user account in COI Risk Manager, so that they can complete a disclosure form. Be mindful that the information you are providing on the COI Certification Sheet uploaded to Cayuse provides our office the information so that when a proposal is funded, we are able to identify those individuals that require COI training. We utilize that information for multiple purposes and, again, for monitoring to ensure that we are compliant, and if we do have any questions, we are able to reach out to the individuals that are named on the form.

David Furman, Information Security & Risk Compliance

- National Security Presidential Memorandum (NSPM) – aka NSPM 33, is a National Security Presidential memorandum that was signed the very last week of the Trump administration. It addresses the security of research being conducted on behalf of the federal funding agencies, specifically NIH and NSF. Another purpose of the memo is to standardize the disclosure process across the federal funding agencies for all research institutions that received at least \$50 million in federal research funding. USA is not yet at that threshold, but we are pretty close to it. We are also in good shape, as far as the requirements for those institutions.
- More importantly, I would like to talk more about the disclosures that are being required and how the NSPM seeks to standardize them. The Council on Government Relations just released this document a couple of days ago that provides guidance for implementation of NSPM-33 (go to ROC website for document). Because the memorandum was signed the very last week of the Trump administration, the Biden administration, when they took office, studied it for a while, made a couple of modifications to it,

and released their proposal for what the implementations should look like. NSPM-33 has not yet been finalized. It is still in the comment and review process, but the administration is hoping to have a final version sometime in April. The chart in the document shows the comparison requirements between NSF, NIH and the NSTC. The first column, NSTC, is the National Science & Technology Council which is under the White House Office of Science and Technology policy. The NSTC is going to be providing guidance for implementation of NSPM 33. This chart shows what needs to be disclosed, and then the rows across the top show the specific point in the process where disclosure is required – the biosketch, current and pending support, project reports, and then post award terms and conditions and other responsibilities. As it goes down, row by row, the chart shows what needs to be disclosed and then where it needs to be disclosed in the process, and then also shows if there is a discrepancy between NIH, NSF; and then the new requirements from NSPM 33. If there are any comments, they can be found in the Notes column on the right side of the chart. This is a good resource for everyone to have, not just what NSPM is going to require once it is fully implemented, but also the current requirements. It highlights where there are some differences between NIH and NSF.

This is a two-page document that has all of the disclosures. But, the following two pages summarizes the disclosures requirements as well as the discrepancies between NIH and NSF requirements, and between those two agencies and the NSPM guidance that will be coming out. It also gives context to all the differences as well. The acronym FGTP in the chart is Foreign Government Talent Programs. As an example, to interpret the chart, it shows that the NIH requires that if you have a foreign contract, you are supposed to provide a copy of that foreign contract as part of your standard disclosures. NSF, however, only requires a copy of the actual foreign contract upon agency request. So, pursuant to the NSF, you have to disclose that you have a contract with a foreign entity but you don't have to actually provide a copy of the contract. The NSPM guidance is going to defer to the agency and it is up to the agency to require whether or not they want to see a copy of that contract.

Question: Some of those requirements, in terms of at the time of proposal or submission, if the information changes during the life cycle of the award, are there requirements for reporting changes other than waiting until the annual reporting period? **Answer:** Currently, it depends upon what those changes are. Some changes require immediate notification to the federal funding agency. Most of those have to do with if you have someone joining the project who has not previously been disclosed. Specifically, if you have new Key Personnel on the project, particularly if they are a foreign national, that needs to be disclosed immediately (David's Note: Effective 10/05/2020, NSF requires immediate notification of any changes to Current & Pending Support, and disclosure of any new projects that require a time commitment, even if no financial compensation).

Upcoming Scheduled ROC Meetings:

Wednesday, March 2, 2022

Wednesday, April 13, 2022