Kristin Ta: Thank you for joining today's presentation on Beyond Grants and Contracts: Other Transactions. My name is Kristin Ta and I'm your moderator for the next 45 minutes. I'm pleased to present our other presenters or panelists. I'll let them go ahead and introduce themselves.

Michelle Bulls: Good afternoon. This is Michelle Bulls, serving as the Director of the Office of Policy for Extramural Research Administration.

Cory Upmeyer: This is Cory Upmeyer. I'm also in that office.

Kristin Wegner: Good afternoon, everyone. Thank you for joining us today. My name is Kristin Wegner and I'm the Lead Policy Analyst for Other Transactions in OER OPERA. I'm just so .. .

Michelle Bulls: So, thank .. . Oh. Go ahead.

Kristin Wegner: No. Go ahead.

Michelle Bulls: No. I was going to say just wanted to give everyone a shout-out and a welcome to all of our attendees. We are really excited to have you as a part of this presentation today. OPERA has added another function within its repertoire. So, you know us for our grants and cooperative agreements skills and we are excited to say that we have added Other Transactions, where we now have the pleasure of having oversight for the policy compliance and training functions of OTs here at NIH. It also serves as a central internal policy function, as I said. We provide the internal training as well we're doing the external training today, internal compliance where the ICs and the program officials at the various institutes and centers provide the external compliance. We also help with determining the appropriate awarding instrument, whether or not the OT is the appropriate awarding instrument to use, aside from our traditional ones, which are grants and cooperative agreements and contracts. And we also provide oversight and chair the Other Transaction Advisory Committee, where we have a plethora of highly functioning professionals, as you all know, here at the NIH, that lead and help us lead some of the OT areas. As well as we have our lead users that work with the eRA OT functionality. And then, we leverage and share resources through a formalized committee under OTAC, which is the Other Transactions Advisory Committee. Cory, you want to give a little bit about yourself now?

Person: You're muted.

Michelle Bulls: Off the mute.

Cory Upmeyer: I apologize. Thank you, Michelle. My name is Cory Upmeyer and I've been in the federal government for about 24 years working as a Program Analyst, Grants Specialist Auditor, Contracting Officer Representative. I've kind of worn several hats, but I have several extensive experience in monitoring grants and FAR-based contracts and serving as a Contract Ops Representative in over seven agencies. I'm now in the National Institute of Health since late 1999, where I served as an Other Transaction Agreement Specialist for the All of Us Research Program and the Aim Ahead Research Program. I'm now an Other Transaction Policy Analyst for the Office of Policy for Extramural Research Administration, and I really enjoy working with my group to work on policy and training and...for OTs in the agency.

Michelle Bulls: Thank you. Cory. Kristin?

Kristin Wegner: Sure. Again, my name is Kristin Wegner and I'm the lead Policy Analyst here at the NIH. Prior to my current position, I had the opportunity to serve as an Other Transactions Agreement Specialist and an Other Transactions Agreement Officer throughout different ICs at the NIH. Overall, I kind of went 5 years of experience working in OT and have been honored to serve and work with Michelle and Kristin Ta in the Policy Division for the past 2 years. So, again, welcome and we're excited to have this time with you today.

Michelle Bulls: Absolutely. Next slide. So, we are really excited because by the end of our time together this afternoon, our goal is that you will be able to actively identify Research Opportunity Announcements for OTs at the NIH, understand how NIH issues central internal policies versus how ICs and programs communicate external requirements, as well as locate NIH's contacts for Other Transactions. And like Kristin kind of talked about initially, we're going to be doing this in a panel style forum. And those of you that know me in the grants and cooperative agreement space, you all know I love to do Q and A's because I think, in my head, that I know exactly what you guys want to know and I'm really ready to tell you, but then I throw a curveball. So, this is going to be really exciting for me and for the team here today. I'm going to try not to throw curveballs, just because this is our first time doing it. But as the rumor has it, I always have to keep it lively so maybe they might throw something at me. But at the end of the day, our goal really is to make sure that you can characterize those Other Transactions, identify the ROAs, discuss the policy implementation for OTs from the extramural standpoint, and locate the contacts for Other Transactions. So, without further ado, we'll get started on slide four. Okay. So, we're going to hit it again. So, what we'll do is, Cory, I'd like for you to start off by talking to us about what Other Transactions are. Can you please explain to us what authorities we have that govern Other Transactions and where they come from?

Cory Upmeyer: That's an excellent question, Michelle. Other Transaction Authorities allow the federal government agencies to enter into the Other Transactions. Other Transaction Authorities have been given to the federal agencies by Congress to provide them with the flexibility necessary to adopt and incorporate best business practices that reflect commercial industry standards into its award instruments.

Michelle Bulls: Thank you very much, Cory. Now, can you tell us this? Define what an Other Transaction is for us. What is an Other Transaction?

Cory Upmeyer: Well, that's kind of a good segue from the authorities, because an Other Transaction is basically a legal, unique awarding instrument. It's not a FAR-based contract. It's not a grant or a cooperative agreement. They're not subject to the Federal Acquisition Regulation or grant regulations, and although .. . unless otherwise noted for certain provisions and the terms and conditions of the award. They are, however, subject to the Other Transaction Authorities that govern the initiative and/or programs as well as applicable legislative mandates and are used to promote unique research initiatives and opportunities.

Michelle Bulls: Thanks, Cory.

Cory Upmeyer: Kristin, now that we have a definition of Others Transaction Authorities and Other Transactions, can you share with us how Other Transactions actually commenced?

Kristin Wegner: Sure. Thanks, Cory. So, in a brief .. . I have to give you all a quick abbreviated history lesson for us to understand the commencement of Other Transactions. So, let's all think back to the "race to space." So, as some of us remember, on October 4th, 1957, the first satellite to orbit the earth crossed the night sky. The Soviet Union's successful launch of Sputnik set the pace for an intense space race with United States. Seeking to reassert its technological superiority over the Soviet Union, the United States launched its first rocket from Cape Canaveral on December 6th, 1957. But the rocket's thrusters failed within seconds and it fell back to earth. These events demonstrated the government's need for faster technology acquisition to maintain competitiveness. So, at that time, president Dwight Eisenhower responded to the rocket's blast by asking Congress to establish a civilian agency with a space exploration mandate. So, on July 29th, 1958, Congress passed the National Aeronautics and Space Act, thus establishing the National Aeronautics and Space Administration, referred to as NASA. In passing the Space Act, Congress granted NASA broad acquisition authority to achieve its objectives, including the authority to enter into Other Transactions as may be necessary in the conduct of its work and on such terms as it may deem appropriate. The act thus created a new kind of awarding instrument called Other Transactions, also known as Other Transactions Agreements, and granted NASA exclusive authority to enter into Other Transactions. So, in the week of the Act's passage, the United States invested extensively in space technology and as we can recall, on July 20th, 1969, less than 12 years after the passage of the Space Act, NASA successfully landed the Apollo 11 astronauts on the moon. So, even though the purpose of enabling NASA to use OTs was to expedite acquisition of cutting edge technology, today, Other Transactions Authorities have been extended to other agencies, including ours for a number of purposes from prototypes to research. So, that kind of gives us a little bit of background of how this all got started.

Michelle Bulls: Thanks, Kristin. We're hearing a bit of an echo from your presentation. I don't know if you should turn down your computer or what. And then, we're going to have, if you could turn the controls over to Kristin Ta, she can actually go ahead and run the slide deck so that folks can see the information on the slide as we're going.

Kristin Ta: And, Michelle, while were switching that over, we have a few questions in the Q and A that you might be able to help us with. Can you talk a little bit about whether Other Transactions are considered a system's award?

Michelle Bulls: So, that'll be discussed further down in the slides, so let's get through the slide deck and then we will answer questions after that point.

Kristin Ta: Of course.

Michelle Bulls: But if you could please take over the controls and work the slides, that would be great. So, the slide deck now .. . I think you all should be able to see that and this is kind of where Kristin Wegner was going from Congressional authorizations by many federal departments on the use of Other Transactions. Very nice history and really, really, really interesting. And I thank Kristin Wegner for that. All righty. So, on slide seven, now, the .. . I think, Cory, this is for you?

Cory Upmeyer: Yes. Yes, Michelle. Thank you very much, Kristin. Now that we know how OT started and that there are other federal agencies that have Other Transactions Authority .. .

Kristin Wegner: Yeah, Kristin, if you could back up one slide. So, since 1958, Congress has authorized many federal .. . So, often times we get asked those questions, so I kind of like to give a little bit of a history with this. Since 1958, Congress has authorized many federal departments and agencies to use Other Transactions Authorities. This list isn't full, but just so you guys know, it includes the Department of Defense, the Department of Energy, the Department of Homeland Security, the Department of Transportation, the Federal Aviation Administration, and the Department of Health and Human Services, and our National Institutes of Health. Just a fun fact is that the first HHS/NIH Other Transaction Authority was extended in 1972 to then the National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program, now NHLBI. Since then, the NIH has received additional Other Transactions Authorities and we'll dig into those next. So, on that note, Michelle, can you please share with everyone a little bit about NIH's Other Transactions Authorities?

Michelle Bulls: Absolutely. So, the question is whether or not I can share about some of NIH's Other Transactions Authorities. So, on the slide, we have three. And currently, there are only three active Other Transactions Authorities, but the great thing you'll know is that that first bullet listed, that lists our authority, is NIH's broad legal authority. It allows the ICs, all ICs at the discretion of the IC director to use an Other Transaction awarding instrument to further promote the IC's mission, NIH's mission using this unique transaction. And so, that's the great thing that, while not each and every Institute and Center or each and every program that is managed by the NIH has a specific authority, we now have a broad authority that the NIH director has a unique opportunity to maximize research initiatives. Also, the second authority listed is specific to the National Heart, Lung, and Blood Institute, also known as NHLBI, and allows the NHLBI's IC director, at his or her discretion, to use Other Transactions to conduct the NIH NHLBI's mission and functions. It also informs the NHLBI on how to carry out the program under policies that are established by the director of NIH and allows them to enter into contracts leased as cooperative agreements and Other Transaction as necessary in order for the director to conduct and promote his or her functions. And then, the final authority listed is specific to NCATS. NCATS has an authority that informs us that if the director of NCATS determines that the goals and the objectives of the section cannot be adequately carried out through our traditional mechanisms, which are grants, cooperative agreements, and contracts, that he or she has the flexibility and the flexible research authority to use Other Transactions to fund projects under the Cures Acceleration network. So, not every IC .. . I'll just tell you. Not every IC opts to utilize the Other Transactions awarding instruments and they're for varying reasons. From some to a huge tap and lift on human resources, to the hesitation with the lack of guardrails, such as regulations and policies, and we'll get into a bit about that in a minute.

Kristin Wegner: Great. Thank you so much, Michelle. That really provides good insight to how we can work with Other Transactions at the NIH. Michelle, can you also talk a little bit about a couple of initiatives that have used Other Transactions, the transactions awarding instrument here at the NIH?

Michelle Bulls: Sure. So, NIH has 25 initiatives using Other Transactions at the moment. So, as I've stated, while some of our ICs are not utilizing them at the maximum availability, many are. So, within the OD, we have the All of Us Research Program which, as you know, the goal there is to ensure better health for all of us, both individually and collectively. And then, the All of Us Program is unique for many reasons including its size, commitment to diversity, and the belief that the participants should partner the partners in research. Also, within the OD, we have our Common Funds, which we call the SPARC Program, which seeks the opportunity to accelerate and develop therapeutic devices that modulate electrical activity and nerves to improve organ functions. And this program was one of the first that I've actually worked on under the OT Authorities and actually worked with the program to establish it. Really neat. Its therapeutic strategies also known as bioelectronic medicine, and it could offer new treatment options for diverse diseases and conditions, such as hypertension, heart failure, gastro disorders, type 2 diabetes, and inflammatory disorders and more. So, that's a really .. . another really neat program and unique program that our OTs have taken advantage of. And then, at the NHLBI, we have the Cure Sickle Cell Initiative, which is a collaborative patient-focused research effort designed to accelerate promising genetic therapies to cure sickle cell diseases. And so, with that, it brings ways to advance research and bring together the sickle cell disease community, patients, advocates, caregivers, providers, researchers, industries, industry partners, and others. And that is just an amazing holistic standpoint for how we cure and execute the research efforts. And then, of course, we have a few others which are Aim Ahead, which is a consortium. We already talked about the All of Us Research Program. Bridge to Artificial Intelligence, which is a really neat one. We have one that's helping to end addiction long-term, which is our HEAL program. And then NCATS has a biomedical data translator program, which is a really neat one. And then, one that I found really exceptional is the NHLBI BioData Catalyst Program. So, there are several .. . Like I said, several initiatives under the OT space that we are monitoring and managing within the NIH. Next slide. So, while it's important to understand our Other Transactions Authorities, it's also important for us to know the difference between the other NIH awarding instruments. So, Cory, I'm going to pivot to you and ask that you please share with everyone the difference between a grant, cooperative agreement, contract, and Other Transactions.

Cory Upmeyer: Thank you, Michelle. Essentially they're all mechanisms to get money to do things, but to start with a grant is a financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. It's used whenever the National Institute or Center anticipates no substantial programmatic involvement with the recipient during the performance of the financially assisted activities. Grant management staff and recipient follow the Office of Management and Budget's Uniform Guidance and our NIH Grants Policy Statement. Whereas a cooperative agreement is just like a grant, but instead of limited oversight, it has substantial federal staff involvement. So, the next area is a Federal Acquisition Regulation Procurement Contract and it's a legal binding instrument to acquire goods and services for the direct use or the benefit of the government. Applications are reviewed on stated evaluation factors and there is a lot more government oversight and control. Deliverables are expected and contracting officers and awardees follow the Federal Acquisition Regulations, also known as the FAR. As aforementioned, Other Transactions are not grants, they're not cooperative agreements, and they're not procurement contracts. An Other Transaction is a legal binding instrument used for a broad range of research and activities. It is determined by statute as well as the opportunity announcement. Applications for Other Transactions go through a scientific evaluation or an objective review. Each term and condition is subject to negotiation. The amount of involvement by federal staff will be negotiated and written in the terms of the agreement. The types and number of reports will be negotiated and written into that agreement. So, overall, while Other Transactions may appear to have fewer restrictions than other types of awards, as they do not follow the Uniform Guidance or the FAR, they still must be awarded in a manner that ensures proper stewardship of federal funds and comply with requirements applicable to all of federal funding regardless of the funding mechanism. Next slide, please.

Kristin Wegner: Great. Yeah, Cory, that was really helpful. Thank you. Michelle, can you talk a little bit about why Other Transactions are typically used instead of the traditional funding mechanisms here at the NIH?

Michelle Bulls: Yup. Absolutely. So, at NIH, the OT mechanism is used when the approach to science or research cannot be done by our traditional awarding instruments. Many of our agreements really include projects where the science is expected to be highly evolving, and with requirements for additional aims and expertise to be added or removed throughout the life of the project after the term is executed. And because of that and the need for flexibility to negotiate those terms and conditions, it's appropriate for the specific program requiring that fluid implementation. It might need to be stood up or taken down on a dime, and being able to have that flexibility and working across partnerships as we've learned some of our authorities allow us to engage with our advocates, our patient population, and others. And we want to be able to do that in a very nimble, in a very flexible, and a very fluid way. And having that ability to do that through Other Transactions is truly an honor and exciting for the NIH and for our recipients.

Kristin Wegner: Oh, my gosh. Indeed, Michelle. The flexibility and fluidity is so important. Thank you so much for hitting on that. And this is exciting. So, with that, Cory, can you have everyone understand where they can locate opportunities for Other Transactions?

Person: You're muted.

Cory Upmeyer: Sorry about that. That's another great thing about Other Transactions. They have the initiative to have flexibility where they publish their opportunities for the Other Transactions. These may include but are not limited to the center, institute, or office, or initiatives' website, to sam.gov, to an industry based distribution, and websites. Okay. Next slide, please. So, Kristin, can you talk to us about how one can apply if interested in an opportunity?

Kristin Wegner: Sure. Thanks, Cory. For everybody to know, each Research Opportunity Announcement, no matter where it's posted, should provide specific instructions for what one should include in their application. So, it's going to look a little bit different per each opportunity announcement. However, I just want to note that all NIH OT applications to be considered for Other Transactions are required to be submitted through NIH's Electronic Research Administration Application Submission System and Interface for Submission Tracking Module, as many of you know as eRA ASSIST. An application guide for specific OT applications is available online at the website we have posted here. And if you guys have more questions about that later, feel free to contact us. What's really important to understand is that these instructions, if you're familiar with our grants, they're going to be different than those that you have for a grant, so make sure you look through those. Things that are required for grants may not be required at the time of application for Other Transactions. Should anyone have questions about their applications, they can reach out to the contacts listed on the opportunity announcement or to the eRA service desk by submitting a web ticket or calling them. If you do reach out to the eRA service desk, I also recommend indicating that you're requesting assistance for an Other Transaction application because they are different than a grants application, so it's clear from the beginning of the request being made. I think that is key for these. I do know that all applications for Other Transactions are required to go through eRA ASSIST.

Cory Upmeyer: Well, thanks, Kristin. So, Michelle, after organizations apply, can you just talk to us a little bit how the applications are reviewed or evaluated?

Michelle Bulls: Absolutely, Cory. And so, unlike our traditional grant and cooperative agreements, the Other Transaction applications go through what we call an objective review, or what we've coined as a scientific evaluation, to ensure that the applications that come in are meritorious and are not watered down because it's not a part of the regulatory peer review requirements. The process involves a thorough and consistent examination of those applications based on an unbiased evaluation of scientific and technical merit and other relevant aspects. The objective review is performed by experts in the field and they also are experts that have the scientific background in order to rank these applications as they need to be ranked. The other thing that I want to make sure of is that while we might not have that peer review aspect from the regulatory standpoint, individuals who serve on our OT objective reviews or our scientific evaluations may be internal and/or external experts, but each review or evaluation will have criteria and composition to ensure that the integrity and the fairness and the transparency of the objective review or scientific evaluation has occurred without bias. All of our peer review principles that we follow for grants and cooperative agreements are definitely embodied, and therefore, even with a conflict of interest among those serving as reviewers is not allowed. And everyone that's involved in our objective review or our scientific process must be protected under the confidentiality of comments from the objective reviews and the scientific evaluations. So, we take it very seriously and it's a process that we have worked very hard to infuse integrity into. And so, Kristin, can you talk to us a little bit about what staff are needed to work on OTs?

Kristin Wegner: Yes. Of course, Michelle. So, it's really important to know that OTs just aren't done in a silo. It takes a team of people to work on these. So, we understand it's going to depend on the type of OT that it is, but there may be many folks working on an Other Transaction award. It can be anybody from compliance leads to initiative leads, program analysts, program leads, program managers, project team leaders, project managers, scientific program directors, strategic coordination reps, technical officers, among so many others. But one thing we do want to point out that is a requirement for our Other Transactions is that there's a minimum amount of folks that need to be on an award from the NIH side as well as from the recipient side. So, at a minimum, an OT recipient must have a Business Official and a Principal Investigator or Principal Director. For OTs, these two roles actually may be the same individual, however most of the time there is a separation of roles at an organization between the Business Official and the PI/PD or multiple PIs and PDs on the award. At the NIH, at a minimum, OT award must be managed by an OT Agreements Specialist, an OT Agreements Officer, and an OT Program Official. And I'll go through the definitions real quick just so you have an understanding of these folks. The recipient Business Official would be on your end. It's the individual named by the applicant who is authorized to act for the organization and to assume the obligations imposed by the federal laws, regulations, requirements, and conditions that apply to the Other Transaction. This individual, if you're familiar with eRA, may be equivalent to the Signing Official, the SO in eRA. For the recipient Program Director or Principal Investigator, this is the individual or individuals designated by the applicant to have the appropriate level of authority and responsibility to direct the project or program to be supported by the OT. Applicants may designate multiple individuals as Program Directors or Principal Investigators to share the authority and responsibility for leading and directing the project. However, when multiple PDs and PIs are named, each is responsible and accountable to the applicant and collaborating organizations for the proper conduct of the project or program, including the submission of all the required reports. The presence of more than one PD or PI on an OT diminishes neither the responsibility nor the accountability of an individual PD or PI. So, each PD or PI will be listed on an OT, and this is different than for those of you who are familiar with grants. For our communication sake, for OTs, we place all PIs and PDs on the award on communication so everybody's on the same page. For the NIH side, the Other Transactions Agreement Officer is a certified federal employee authorized to execute Other Transactions on behalf of the government. The Agreements Officer is responsible for legally committing the government to an OT and they can enter into, administer, and terminate the Other Transactions. The Other Transactions Agreement Specialist is a federal employee who serves as a delegate of the Agreements Officer. They are typically assigned to the responsibility of the day-to-day administrative management of the OTs. And so, if you receive an OT award, you may be more in correspondence with the Agreements Specialist than the Agreements Officer for the day-to-day management of the award. And we also have the Other Transactions Program Official, and this is a federal employee that is responsible for the programmatic, scientific, and/or the technical aspects of the Other Transaction. And within the OT, it'll typically be defined out each of these roles so you know who is responsible for what in the OT.

Michelle Bulls: This is really, really good information and someone in the panel .. . or not the panel, but one of the folks asked if there .. . Our participants asked if this information was going to be included into the slide deck, and so we will definitely add an appendices section to our slides, so that we can put this helpful information in it for you guys. So, thanks a lot, Kristin. Cory, pivoting to you, can you now talk to us about how Other Transactions Agreements are written?

Cory Upmeyer: Yes. Definitely. When I had the background in grants and contracts, basically everything is boilerplate, but Other Transactions are based off of the application, the review and evaluation, and needs of the National Institutes of Health, and the negotiations between the NIH and the applicant. So, this is really unique to this awarding instrument, because every term and condition can be negotiated for the award. And negotiations are a process that involve discussing and reaching to an agreement on the terms and conditions for an Other Transaction. Throughout the negotiation, it's important that the recipient Business Official and the National Institutes of Health OT Agreements Officer be present throughout each step of the negotiations for each potential award. Depending on where the project falls on the research spectrum, the ability to establish allowable costs, schedule and performance requirements will vary from best effort to clearly identifiable and enforceable requirements. The negotiated terms and conditions must be appropriate for each Other Transaction, and in negotiating terms and conditions for each OT, sometimes restrictions are imposed by appropriations and policy requirements based on that type of activity and compliance obligations must be considered. So it's a different way of thinking than grants and FAR-based contracts, which are very standardized and set.

Michelle Bulls: Yeah. I think that's true and as we've talked about it before, in the grants and cooperative agreements space, a lot of times the only time we are able to really kind of add those unique principles and pieces is when we have the specific award conditions. And so, when we have the OTs, these are .. . What do we say back at the ranch, right? One OT is one OT. So, the agreements terms are going to be very different for each. So, I want to thank you for that, Cory. Kristin, can you talk to us about what types of terms and conditions are in the Other Transaction Agreement as outlined here on the slide.

Kristin Wegner: Sure. Thanks, Michelle. I was also .. . Good going because I was going to also say that we always say one OT is one OT as they're not standard and they do look so different. But even on that, so each .. . So, what we do is have a requirement of what needs to be written into the Other Transaction Agreement, but it can look different. So, when we look at the screen, each issued Other Transaction will be written and include in no particular order, but not be limited to the following sections. So, it'll have the OT identification number, the parties involved, what Other Transactions Authority is being used, the description of the project, the term of execution, how the termination will be done, how any modifications will be done, how you'll do the accounting and management of it, how it'll be funded. It'll also talk about the obligation and payment, if there's any cost sharing involved. It'll talk about how if .. . It'll talk about how it'll take care of audits and disputes. It'll mention all of the different statutes and regulations that are applicable to all of our federal awarding instruments, including an OT. It'll talk about flow down, so if you have subrecipients on an award or contractors, how that may look. It'll also talk about how reporting will be done or how deliverables will be given. It'll note any restrictions and then it'll also include how the closeout will be done on the award. It's really important, kind of as a side note, that the Business Official who signs the award understands each term and condition on the award and that goes back to the negotiations Cory talked about. So, when you have those negotiations and you're reviewing it, make sure it is completely clear for you. Additionally, in my opinion, it is critical that your team who works on an OT know what is written into the agreement and any modifications thereafter. Since OTs are not bound to the FAR or to Uniform Guidance, it's extremely important for everyone involved to know what is agreed to in the Other Transaction Agreement. So, kind of gives us an overview of what that looks like and what we should pay attention to.

Cory Upmeyer: Woo. Thanks, Kristin. Say, now that we've been doing OTs for a little bit awhile, Michelle and Kristin, can you tell me a little bit of some of the lessons learned from the agency and some of the perspectives from our ICOs that are working on Other Transactions?

Michelle Bulls: Sure. Kristin, I'm going to let you start and I'll end. Thank you.

Kristin Wegner: Thanks, Michelle. So, I've kind of .. . I'm going to share with you all some things based on my experience when I was an Agreements Special .. . Specialist and Agreements Officer. And I'll kind of touch on a few things I mentioned before, but I'm going to highlight these because I do believe they're super important. First of all, as was mentioned by Michelle earlier, the purpose behind OTs is flexibility and adapting to our process and agreement to fit the circumstances that we're facing at the moment. So, to be aware of that going into it. From my experience working on OTs, there was a huge time commitment as these awards were evolving and modifying through time. And so, on that note, just to think about .. . If you're thinking about applying to an award or you're thinking about who would be the PI or who would be the Business Official, ensuring that they have the time commitment to dedicate to this type of an awarding instrument. For us, at the commencement of the pre-award cycle, we needed to set aside time, significant time, to devote to our pre-award meetings that was internally and externally and to negotiate that agreement. Throughout my experience on the OTs, there was often more than just the Business Official involved in negotiation process, and so that's something that's different than for those of you involved with grants, where sometimes you can just take it and run with it. Often times when we would send the agreements to be reviewed and start that negotiation process, there might be senior leadership, there might be attorneys, there might your supervisor, so there were various people involved. And every institute, every organization, every entity that we worked with was a little bit different, but that was both on the recipient side and the NIH side because it is an agreement and it is being negotiated. Folks need to see that and they want more eyes on it. So, make sure if you plan for these, that you build in the appropriate team and eyes and time to review that. Also, kind of unlike grants, Business Officials shouldn't assume that "any" office's official in one's office can review an OT award or its modification. It's really important to distinguish the differences so that Business Officials who work on OTs understand the difference between them and grants and contracts. Sometimes I would have folks say, "Oh, this person can just sign it." It would be .. . recipient really wants someone just to sign it without understanding the full agreement that was agreed to before and then the next modification of that. Another thing, as I alluded to earlier, another piece that I always like to remind folks of is that all parties, team members must understand OT agreement and all succeeding modifications. Again, I mentioned this before, because they're not bound to the FAR Uniform Guidance, everyone should understand what is written into the agreement. What are the goals, what are the milestones, what can we, can't we do, what are the requirements, what's the reporting looking like to do that? Oh, and I just got a note that we have 1 minute left, so I'm not going to go through anything else. Michelle, I'm going to turn it over to you to talk about the agency side.

Michelle Bulls: So, one of the things that I think that has been very enlightening for the OT Authorities is to be able to work with the recipients in a much different venue. Where we have to get a prior approval for many things, where we are not able to quickly pivot in the research because of administrative requirements, that's not so with the OTs. The OT instrument, awarding instrument, to me, really does drive the science versus the administrivia driving the science or hindering the science, if you will. And so, for us, being able to be a part of some of the discussions related to the program designs, understanding the needs and the outcomes from the scientific aspects, and then being able to work closely with our nontraditional partners and some traditional partners to make that happen in a way that is not administratively burdened down by regulations, either the FAR or the Uniform Regulations for grants. It's something that I've found very unique, very attractive, and it really has helped the evolution and the uniqueness of the research opportunities, as we've said all along. So, I do believe that there is just a wonderful unique opportunity for NIH to enter into this space with our recipients and our OT community in ways that we've not had to have the opportunity to do it before. And it's all through negotiations of the terms and conditions of the OT awards, understanding what that baseline science is and the outcome, how quickly and how nimble we need to be to make that happen. That's really the beauty of the OT and that's really the beauty that I've seen as I've been partnering with our programs across the enterprise to make these happen. And with that, Kristin Ta, I will turn it over to you.

Kristin Ta: Great. So, thank you so much to our presenters and participants for a great session. I know we have several questions in the Q and A that we weren't able to get to, so we'll make sure we get those downloaded so that we can post responses for you all. If you still have additional questions, please visit our exhibit hall staff for chat and one-on-one opportunities, and you can also find contact information in the help section of our grants.nih.gov website. Your feedback on this presentation is very important, so please take a moment to let us know what you thought by clicking on the session feedback button located with the description and presenters on the auditorium list of sessions. When you're completely done with the seminar, please also complete the overall survey form in the navigation bar at the top of the page. Thanks again, and I hope everyone has a great day.