

Agenda



AGENDA

This agenda represents the programming in the seminar auditoriums. For a full schedule that includes timed events happening at booths, see our <u>Master Schedule of Events</u>.

Click on the links below to view events for a specific day and time.

TUESDAY / OCTOBER 27, 2020

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TUESDAY / OCTOBER 27, 2020

1:00pm EDT

Auditorium A - Plenary

Extramural Research: Money, People, and Science

Keynote with Dr. Michael Lauer, NIH Deputy Director for Extramural Research

Kick-starting the seminar, Dr. Michael Lauer, NIH Deputy Director for Extramural Research, shares his experiences and perspective on the role of NIH in encouraging and supporting biomedical and behavioral research across the globe.

Objectives:

Upon completion of this session, participants will be able to:

- explain the general role of NIH in support of biomedical and behavioral research;
- explain the evolving ecology of biomedical research and how it affects NIH's ability to issue awards; and
- describe how NIH is thinking about becoming a federal science agency that excels at managing by results.

2:00pm - 2:45pm EDT

Auditorium A / Track A - NIH Grants Process

Fundamentals of the NIH Grants Process and Need-to-Know Resources

Every successful journey starts with a good foundation. If you are new to working with NIH, this video will answer key questions. Where do I start? Where's the funding? Where do I turn when I need help or advice? What opportunities are available and how can I find them? What's the application process and how long does it take? We will walk you through the grants process and give you an overview of key resources and websites you will need to be successful.

- describe the organizational structure of NIH and ways it can aid in locating funding opportunities and staff contacts;
- provide a high-level explanation of the path NIH grant applications take from submission to award; and
- find answers to your questions after the seminar, whether it be knowing the right website, hel desk, or staff contact.

Auditorium B / Track B - NIH Policies and Programs

Current Issues at NIH: Grants Policy Updates

Don't miss this opportunity to hear about what is new and being developed within the National Institute of Health's (NIH) programs, policies, and budgets. In this comprehensive review, participants will learn about the newest policy updates and how their respective institutions may be impacted. Upon completion of the presentation, participants will have the opportunity to ask questions about new and existing policies. Topics include recent and upcoming changes to NIH policy, compliance requirements, and so much more!

Upon completion of this session, participants will be able to:

- demonstrate an understanding of the NIH grants policy requirements;
- identify the source of policy requirements; and
- provide examples of current issues at NIH.

Auditorium C / Track C - Let's Talk About It

Open Mike with Dr. Michael Lauer

Dr. Michael Lauer is the NIH Deputy Director for Extramural Research and author of the NIH blog, "Open Mike." The format for this session is an informal Q&A where the audience determines the course of the discussion. Dr. Lauer will use your questions to provide a more personalized and candid conversation about what is on the mind of senior NIH management and what is happening at NIH.

3:00pm - 3:45pm EDT

Auditorium A / Track A - NIH Grants Process

Navigating NIH Programs to Advance Your Career

Career Development Timeline

Find out which NIH funding mechanisms apply to you throughout your career. This talk covers many of the mechanisms that apply to Ph.D.'s and M.D.'s (or equivalent research and clinical doctoral degrees), from graduate/medical school through your early-stage faculty years.

Predoctoral Students and Postdoctoral Researchers

This session will describe different types of NIH grant that support mentored research training including fellowships, institutional training grants and career development awards.

Early-Stage Investigators (ESIs)

Do you have less than 10 years of research or research training experience following your terminal research degree or medical residency/fellowship? What is NIH doing to encourage ESIs? Come to this session and find out what your next step should be when it comes to NIH funding.

Objectives:

Upon completion of this session, participants will be able to:

- identify what kinds of NIH grant support (fellowships, career development (K) awards, research grants) are available based on career stage and training experience;
- explain the benefits of additional mentored research; and
- describe funding opportunities for transitioning to an independent position.

Auditorium B / Track B - NIH Policies and Programs

Research Involving Animals: OLAW

Are you considering using live vertebrate animals in your research? Are you aware that the policies and regulations regarding research animals are different than those involving human subjects? This session provides information on the requirements for using animals, appropriate completion of the Vertebrate Animals Section of the grant application, the functions of an Institutional Animal Care and Use Committee, details on the various Assurance documents, and the consequences of what happens when animal activities become non-compliant.

Upon completion of this session, participants will be able to:

- Define live vertebrate animal:
- Describe requirements of the Vertebrate Animal Section (VAS);
- Recognize significance of verifying Institutional Animal Care and Use Committee (IACUC) approval;
- Identify three types of Animal Welfare Assurances; and
- Describe non-compliance and understand its implications.

Auditorium C / Track C - Let's Talk About It

Advanced Administrative Topics: Pre-Award Issues

ADVANCED ADMINISTRATIVE TOPICS: PRE-AWARD ISSUES

This is a case study driven session designed to provide insight into how NIH works with grant recipients to solve unusual problems that can arise before an award is issued and at the non-competing renewal stage.

- Understand how NIH approaches unusual problems and scenarios that arise in grants administration
- Understand options in solving pre-award problems and issues

4:00pm - 4:45pm EDT

Auditorium A / Track A - NIH Grants Process

Grant Writing for Success

Are you a new or junior investigator? Do you assist in the preparation of the scientific portions of an application? If you answered "yes" to either question, then don't miss this popular presentation from NIH experts that provides insights and helpful hints on preparing an application for submission. Learn how to avoid the most common mistakes in writing grant applications and correct some typical misconceptions about the grant review process.

Objectives:

Upon completion of this session, participants will be able to:

- list significant steps involved from application to award;
- explain the fundamentals of writing a clear and concise research grant application; and
- locate resources to facilitate the grant-writing process.

Auditorium B / Track B - NIH Policies and Programs

International Organizations and the NIH Grants Process

As research becomes more global, international collaborations become more necessary. Researchers are being faced with issues and concerns in which they have little experience. This session will answer such administrative questions as... What are possible issues when a collaborator is foreign? Are there issues that may be unique to resource poor countries? Differences in the review process for foreign applicants will also be addressed.

Objectives:

Upon completion of this session, participants will be able to:

- explain basic processes for establishing international collaborations; and
- describe recent updates and changes to related NIH policies for foreign grants.

Auditorium C / Track C - Let's Talk About It

Waddayawannaknow? Ask a GMO!

Time to take advantage of a whole lot of NIH grants management expertise in one room at the seminar! We've gathered several of our NIH Chief Grants Management Officers from the seminar for this 45-minute Q&A to help answer some of your final administrative questions of the day. Don't miss this unique opportunity!

5:00pm - 5:45pm EDT / AFTER HOURS CONVERSATION

Auditorium A

Scientific Workforce Diversity in Extramural Research

Descriptor:

Literature shows that diverse research teams foster enhanced scientific innovation and discovery, improve the quality, depth, and breadth of research conducted, raise new questions and offer improved perspectives and outcomes. While this viewpoint is widely accepted, greater inclusion of individuals from historically underrepresented populations in STEM continues to be a troubling and on-going issue. This session will help attendees to better understand how NIH, through utilization of available research training and career development funding opportunities, intends to impact opportunity gaps and improve representation of underrepresented populations in STEM within the extramural scientific workforce.

Objectives:

- learn about some of the issues related to diversifying the extramural research workforce;
- gain a better understanding of how to plan for and capitalize on different funding opportunities to grow your career (i.e., what should I apply for in grad school, as a postdoc, as an early stage investigator?
- learn more about how to navigate the NIH funding process and become more familiar with prgram officers associated with several diversity-related funding mechanisms.

WEDNESDAY / OCTOBER 28, 2020

1:00pm - 1:45pm EDT

Auditorium A / Track A - NIH Grants Process

Rigor and Reproducibility: Back to Basics

One of NIH's goals is to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science. The NIH initiative to Enhance Reproducibility through Rigor and Transparency clarifies a commitment to this goal. Attendees of this session will gain a better understanding of the updates to research grant and career development award application instructions and review language that includes increased attention to scientific premise, scientific rigor, consideration of biological variables, such as sex, and authentication of key resources, such as cell lines.

Upon completion of this session, participants will be able to:

- describe the issue of reproducibility and NIH plans to address it;
- summarize changes to application instructions and review criteria for NIH grants; and
- explain how the policies behind rigor and transparency will impact different types of grants along with the implementation timeline.

Auditorium B / Track B - NIH Policies and Programs

Understanding NIH Career Development "K" Awards

NIH Career Development (K) awards provide research training opportunities for both research scientists and clinicians at various stages of their careers. NIH Grants Management & Program Officials will describe the various career award mechanisms and cover policies that apply to these awards. Developed for administrators, but investigators may also be interested.

Upon completion of this session, participants will be able to:

- accurately identify at least two types of NIH Career Development ("K") Awards; and
- describe three features of this type of award.

Auditorium C / Track C - Let's Talk About It

Commitment Transparency

In this session, recipients will learn about their critical role in providing complete, transparent information about investigators' financial support and affiliations, and how NIH uses this information to

ensure that NIH's funding decisions are fair and appropriate. We will discuss NIH requirements and expectations for the disclosure of all research support including other support, foreign components, in-kind, and other resources.

Upon completion of this session, participants will be able to:

- describe the ways that NIH collects information regarding affiliations and research support;
- define Other Support, and describe the monetary and non-monetary resources that must be disclosed; and
- understand the definition of a foreign component.

2:00pm - 2:45pm EDT

Auditorium A / Track A - NIH Grants Process

Budget Building Blocks for Investigators

There is much for an investigator and project administrator to consider when developing a budget for a grant application, such as what can be requested, how is the budget calculated, and is the request appropriate. NIH Program and Grants Management Officers will guide you on finding the answers to these questions by providing valuable information for preparing a proper grant budget.

Upon completion of this session, participants will be able to:

- explain the major differences between modular vs categorical budgets;
- list the most common budget submission errors;
- list pre-award costs and post award actions; and
- develop and justify budget requests for grant applications.

Auditorium B / Track B - NIH Policies and Programs

How Changes to Title 2 Code of Federal Regulations Affect You

Coming Soon

Auditorium C / Track C - Let's Talk About It

Writing an Effective "K" Application

This session will provide an overview — along with insights and helpful hints — on preparing a mentored career award (K award) application for submission to the NIH. It is designed for junior investigators and those who assist in the preparation of the scientific portions of an application. Learn how to develop a strategy, plan your application, application requirement, and review criteria. In addition, hear advice on how to avoid the most common mistakes in writing K applications and correct some typical misconceptions about the review process.

Upon completion of this session, participants will be able to:

- understand the steps involved from application to award;
- explain the fundamentals of writing a clear and concise application; and
- describe the nuances in applying for a career development (K) award.

3:00pm - 3:45pm EDT

Auditorium A / Track A - NIH Grants Process

Let's Look at Peer Review

What happens after your application has been submitted? How will it be evaluated? This session follows a typical application from submission through peer review to funding consideration, with key steps and important factors to note along the way. Understanding the NIH peer review is fundamental to a successful grant application. So, don't miss this opportunity to know the score on peer review!

Objectives:

- upon completion of this session, participants will be able to;
- describe the two levels of NIH peer review;
- prepare grant applications that correspond to the NIH review criteria;
- understand the NIH scoring system; and
- uphold the core values of NIH peer review.

Auditorium B / Track B - NIH Policies and Programs

Understanding NRSA Fellowships ("F") and Training ("T") Grants

What are the issues specific to grants awarded under the auspices of Ruth L. Kirschstein National Research Service Awards (NRSA), specifically Individual Fellowships and Institutional Training Grants? This session provides administrative and financial aspects of training grants and fellowships.

Upon completion of this session, participants will be able to:

- distinguish between NIH's individual and institutional award mechanisms;
- differentiate stipends from compensation;
- discern allowable and unallowable costs along with re-budgeting authorities for NRSA awards;
- understand NRSA payback requirements and options; and
- identify post-award reporting requirements and submission procedures.

Auditorium C / Track C - Let's Talk About It

Compliance Pitfalls and Strategies for Success: Case Studies

Join NIH experts for an introduction to compliance activities, including an interactive discussion of specific case studies that illustrate common compliance issues. A primer for administrators and interested investigators.

Upon completion of this session, participants will be able to:

- accurately identify and understand key compliance requirements governing NIH awards; and
- make more informed decisions in accordance with policy and regulatory requirements.

4:00pm - 4:45pm EDT

Auditorium A / Track A - NIH Grants Process

NIH Peer Review: "Live" Mock Study Section

Join us for a brief look at what a peer review study section meeting might look and sound like as applications are discussed. During this 45-minute session, you'll get a better idea of how the meeting is conducted, as well as hear a sampling of common questions asked by reviewers and mistakes by applicants. A short Q&A will follow the presentation.

After participating in this session, participants will be able to:

- describe the basic process of what happens to an application during a Peer Review Study Section Meeting; and
- explain the roles of the scientific review officer, program official and reviewers during the meeting.

Auditorium B / Track B - NIH Policies and Programs

NIH Loan Repayment Programs (LRP)

Do you (or does someone you know) have student debt? If so, find out how the NIH Loan Repayment Programs (LRPs) can repay up to \$35,000 each year.

This session is for students, new researchers, and administrators/mentors, who want to learn how biomedical and behavioral scientists with student debt can benefit from NIH's five extramural LRPs and start planning an application.

Objectives:

Upon completion of this session, participants will be able to:

- list the 5 types of extramural Loan Repayment Programs available and their purpose;
- provide general eligibility requirements; and
- describe the peer review process for LRP applications.

Auditorium C / Track C - Let's Talk About It

Advanced Administrative Topics: Post-Award Issues

This is a case study driven session designed to provide insight into how NIH works with grant recipients to solve unusual problems in the post award setting.

Upon completion of this session, participants will be able to:

- Understand how NIH approaches unusual problems and scenarios that arise in grants administration
- Understand options in solving post award problems and issues

5:00pm - 5:45pm EDT / AFTER HOURS CONVERSATION

Auditorium A

NIH Next Generation Research Initiative - Training Future Biomedical Researchers

The National Institutes of Health (NIH) launched the Next Generation Researchers Initiative in 2017 to address longstanding challenges faced by researchers trying to embark upon and sustain independent research careers, and to take steps to promote the growth, stability and diversity of the biomedical research workforce. In this session, the panelists will provide an update on NIH's progress in terms of supporting early-stage investigators (ESIs), as well as discuss some programs and initiatives that have been developed for early career investigators. In addition, we will define and discuss the importance of monitoring "at-risk investigators" (those PIs who have had prior substantial funding from NIH and, unless successful in securing a subsequent substantial competing research grant award, will have no remaining research grant funding) as a new group we are monitoring to stabilize the research funded workforce.

- understand the purpose and intent of the NGRI, as well as NIH targets for numbers of funded next generation researchers over the last 2 fiscal years;
- identify programs for which ESIs are uniquely eligible; and
- understand ESI extension policies to ensure that ESIs who experienced lapses in ability to apply for an R01 may apply for ESI extensions.

THURSDAY / OCTOBER 29, 2020

1:00pm EDT

Auditorium A / Track A - NIH Grants Process

Ready! Set! Submit! Application Preparation and Submission

How do you get your great research idea to NIH for funding consideration? You must find an appropriate opportunity; prepare your application; submit your error-free application through Grants.gov to NIH on-time; and confirm NIH received it correctly. Learn about the NIH grant application process and the NIH resources available to complete each step.

Upon completion of this session, participants will be able to:

- list the organization registrations needed for submission;
- find a funding opportunity announcement;
- format application attachments according to NIH rules;
- discus various documents that provide instructions for completing an application; and
- state the broad steps required to prepare and submit a grant application to NIH.

Auditorium B / Track B - NIH Policies and Programs

Diversity in the Biomedical Workforce

Learn more about diversity in the national scientific workforce, and NIH efforts to expand outreach and recruitment of underrepresented groups applying for support through its policies, processes and programs. Come with your questions and join the discussion about this important issue. You will leave this session with a better understanding of scientific workforce diversity, and where to find funding opportunities and resources designed to support diversity in biomedical research.

Upon completion of this session participants will be able to:

- explain how scientific workforce diversity contributes to the goals of the NIH mission;
- identify sources of information about groups that are nationally underrepresented in science;
- find NIH funding opportunities, and identify funding opportunities that support recruitment and retention of underrepresented groups; and
- locate resources regarding recruitment and retention strategies to support diversity in science, research and leadership.

Auditorium C / Track C - Let's Talk About It

Using RePORT to Understand Who and What NIH Funds

NIH makes an abundance of grant and funding data — including analyses of who and what we

fund — available to the public through a resource called RePORT. Learn how to use this resource to find information to help target your application, find key contacts at NIH and in the grantee community, and more.

Upon completion of this session, participants will be able to:

- search for information on NIH funding by institution, principal investigator, and more;
- identify existing projects NIH is funding on their topics of interest and explain how this information can help prospective applicants;
- demonstrate how to determine which NIH institutes and types of programs are supporting their research topics of interest; and
- explain how to identify which study sections review applications in their specific field.

2:00pm - 2:45pm EDT

Auditorium A / Track A - NIH Grants Process

Notice of Award Arrives...Now What?

What happens at your institution and at the NIH between grant award and closeout? This session will provide new research administrators a better understanding of NIH post-award activities from the perspective of NIH Senior Grants Management Specialists. The emphasis will be on business practices.

Upon completion of this session, participants will be able to:

- describe the key elements of a Notice of Award;
- detail NIH reporting requirements;
- describe grant changes that require prior approval; and
- explain what is required to closeout a grant.

Auditorium B / Track B - NIH Policies and Programs

Research Misconduct and Integrity

The NIH Extramural Research Integrity Officer and an expert from the HHS Office of Research Integrity discuss research misconduct regulations, describe the institution's responsibilities during research misconduct proceedings, and share insights into recognizing potential research misconduct and best laboratory practices that may help to avoid misconduct in research.

- define research misconduct and explain how the NIH and ORI work together;
- recognize questionable research practices vs research misconduct;
- describe the institution's responsibilities in promoting research integrity and handling allegations of research misconduct;
- identify red flags that could indicate research misconduct; and
- explain the interpersonal, institutional and professional responsibilities in the overall ethical conduct of research.

Auditorium C / Track C - Let's Talk About It

Developing and Optimizing Your Mentor Relationships

In this session, we'll review the benefits of networking for career development, and strategies for identifying who should be within your developmental network and when, where, and how to identify those individuals. This session will highlight important strategies for managing your relationships with mentors and others within your developmental network.

Upon completion of this session, participants will be able to:

- define networking and understand the benefits of networking for career development;
- define the at least 3 types of career advisors and their roles within a developmental network; and
- list strategies for developing and optimizing relationships within one's developmental network.

3:00pm - 3:45pm EDT

Auditorium A / Track A - NIH Grants Process

All About Costs: A Post-Award Primer

Looking for an introduction to post-award costing issues? If so, this is the presentation for you. This session will emphasize accounting, monitoring and reporting requirements, and other important topics, while encouraging audience participation. It will be a great post-award primer for administrators and investigators.

Upon completion of this session, participants will be able to:

- identify the various Federal requirements and NIH Policies governing considerations:
- make more informed determinations regarding the allowability of costs on NIH awards; and
- gain an understanding of other cost-related requirements, such as the deadlines for submitting required financial reports and closeout documentation.

Auditorium B / Track B - NIH Policies and Programs

Research Enhancement Award (R15) Program

The NIH Research Enhancement Award program (R15) supports faculty research at campuses that have received no more than \$6 million in total costs of NIH funding in the past 4 of 7 fiscal years. It is designed to support meritorious research, strengthen the research environment of the institution and to expose students to research. This session will focus on NIH's goals for the program and provide perspective on how to write a competitive application.

Upon completion of this session, participants will be able to:

describe the programmatic goals of the R15 program;

- describe strategies that an individual or institution may implement to increase their competitiveness for an R15; and
- identify unique aspects of R15 applications.

Auditorium C / Track C - Let's Talk About It

After Your First Award: Next Steps in Your Journey with NIH

Congratulations! You just received your first independent NIH award. Nothing but success from here on, right? Maybe... Maybe not. The difference can lie in what you do (or don't do) after getting this first award. This session will illuminate possible paths to pursue — and common pitfalls to avoid — to enhance the likelihood of the long-term success of your funded Research Program.

Upon completion of this session, participants will be able to:

- appreciate the value of "big picture" strategies designed to enhance the likelihood of their long-term success;
- realize there is more to a thriving research program than the linear progression of going from grant-to-grant; and
- explain the value of the mentor's role, including your NIH Program Director.

4:00pm - 4:45pm EDT

Auditorium A / Track A - NIH Grants Process

eRA Commons: Interacting with NIH Electronically Post-Submission

The eRA Commons is the suite of software modules provided by NIH for your application and award management. This interactive session looks at various features and functions of eRA Commons as it relates to the grant process and your place in that process.

The grants process is a complex path. Participants will be able to gain understanding about various aspects as we follow the path from application submission to closeout.

Upon completion of this session, participants will be able to:

- Provide a high-level description of eRA Commons reporting tools, including the variants of the Research Performance Progress Report (RPPR), Closeout, and more.
- Provide a high-level description of other eRA Commons features, including: Institution and Personal Profiles, Roles and Delegations, Just-in-Time (JIT), Prior Approval options, and Admin Supplements; and more.

Auditorium B / Track B - NIH Policies and Programs

SEEDing Healthcare Solutions

NIH has launched the SEED Office (Small business Education and Entrepreneurial Development) to

strategically align academic research resources with dedicated funding for small businesses to help entrepreneurial scientists move their promising discoveries through the early product development pipeline. This session will highlight NIH's strategic focus on early product development, resources and opportunities available to academic and small business innovators, and the ways strategic partners and investors and can partner with NIH to access novel technologies.

Objectives:

Upon completion of this session, participants will be able to:

- understand how NIH helps turn discovery into health;
- describe the entrepreneurial support provided by SEED; and
- understand how SEED can help innovators transform science projects into product development projects.

Auditorium C / Track C - Let's Talk About It

Addressing Sexual Harassment in Biomedical Science

NIH is committed to supporting a safe and respectful work environment. Join this panel discussion to learn about expectations for institutions and the individuals supported on NIH-funded awards to foster a harassment-free environment, actions NIH can take to address sexual harassment, and where to find help if you are concerned about sexual harassment at your institution.

Upon completion of this session, participants will be able to:

- explain institutional responsibilities related to preventing and addressing sexual harassment;
- describe actions NIH is taking to reduce sexual harassment at NIH and its awardee institutions;
 and
- alert the appropriate parties with concerns about sexual harassment.

5:00pm - 5:45pm EDT / AFTER HOURS CONVERSATION

Auditorium A

Mentoring: NIH and the National Research Mentoring Network (NRMN)

Mentorship has been shown to be critical for the advancement of biomedical researchers. Join this session to hear about national efforts to advance the science of mentorship. This session will help mentors and mentees improve their practice and expand their mentoring networks to advance their careers.

- Identify your mentoring needs and expand your network to meet those needs
- Read about evidence-based approaches to mentoring
- Use the resources at NRMN and other mentoring sites

FRIDAY / OCTOBER 30, 2020

1:00pm - 1:45pm EDT

Auditorium A / Track A - NIH Grants Process (Note: 1 hour 45 min. block) Simplifying Informed Consent (Presented by OHRP)

In this session, representatives from the Office for Human Research Protections (OHRP) will discuss what goes into a meaningful informed consent. Practical examples will be used to illustrate how to discern meaningful information for potential participants, and how to present information simply in consent documents and materials to ensure consent processes fulfill their goal of enabling potential participants to make informed decisions about whether to participate in the research.

Objectives:

Upon completion of this session, participants will be able to:

- Explain why getting meaningful consent is critical to enrolling research participants;
- Describe some of the important components for a meaningful consent;
- Demonstrate techniques that can be used to simplify consent and create a meaningful document.

Auditorium B / Track B - NIH Policies and Programs

Helping Academics Address Unmet Medical Needs

NIH supports a national network of proof-of-concept centers that enable academic innovators to validate the potential health impacts of their scientific discoveries and advance them toward healthcare products and services to improve patient care and enhance health. The consortium merges the strengths of nearly 100 high-impact research institutions with product development expertise and resources from federal and private-sector partners across 34 states and Puerto Rico. In addition, NIH offers numerous other product development funding opportunities and resources to academic innovators. This session will help academic innovators learn about NIH's product development support through an interactive discussion with the NIH staff.

- understand and identify product development support available to academic innovators;
- describe the goals of the NIH's national network of proof-of-concept centers and what support, both funding and resources, they provide.

Auditorium C / Track C - Let's Talk About It

Digging Deeper into Small Business Programs and Policies (SBIR/STTR)

NIH's Small Business Programs (Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) invest over 1 billion dollars a year into U.S. health and life science companies. Learn about the nuts and bolts of the SBIR and STTR programs and the policies that potential applicants and awardees need to know.

Upon completion of this session, participants will be able to:

- understand the goals, policies, and structure of the NIH Small Business Programs;
- exhibit more confidence in navigating the NIH Small Business Program application process and submitting a competitive application; and
- locate the appropriate NIH websites and contacts to find more information.

2:00pm - 2:45pm EDT

Auditorium A / Track A - NIH Grants Process

Simplifying Informed Consent (Presented by OHRP) (continued)

In this session, representatives from the Office for Human Research Protections (OHRP) will discuss what goes into a meaningful informed consent. Practical examples will be used to illustrate how to discern meaningful information for potential participants, and how to present information simply in consent documents and materials to ensure consent processes fulfill their goal of enabling potential participants to make informed decisions about whether to participate in the research.

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Auditorium B / Track B - NIH Policies and Programs

From Bench to Boardroom: Support for Small Businesses

NIH's Small Business Programs (Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) are the largest sources of early-stage capital for life science technology commercialization in the United States. NIH invests over 1 billion dollars a year to help convert promising technologies into the products needed by patients, clinicians, and caregivers. This session will help innovators understand what funding and support are available through these programs

and how to navigate the application process through an interactive discussion with NIH Small Business Team staff.

Upon completion of this session, participants will be able to:

- describe the goals of the NIH Small Business Programs and what support, both funding and resources, is available;
- navigate the NIH Small Business Program application process and submit a competitive application; and
- identify appropriate NIH contacts during the application process.

Auditorium C / Track C - Let's Talk About It

Data and Resource Sharing: Firming Foundations for Future Frontiers

Research data, resources, and other findings establish the firm foundations upon which future frontiers of research build. Accordingly, the rapid sharing of data and research resources has been a key factor in accelerating scientific inquiry to further advance research and discovery. NIH funded institutions and investigators are required to understand and comply with NIH policies under their NIH funding agreements. This session will describe and highlight NIH policies and challenges for data and resource sharing, as well as what is expected of NIH funded institutions and investigators to comply with their funding requirements.

Upon completion of this session, participants will be able to:

- understand the history and longstanding commitment of NIH and policies to data and resource sharing for advancing research and discovery understand the importance and implementation requirements of the NIH Genomic Data Sharing (GDS) policy; and
- understand the critical role and responsibilities of NIH funded institutions and investigators in accelerating scientific inquiry and discovery through appropriate sharing of data and resources from NIH funded research.

3:00pm - 3:45pm EDT

Auditorium A / Track A - NIH Grants Process

An Overview of NIH Policies on Human Subjects Research

This session will introduce you to the NIH policies that apply to research involving human subjects, including clinical trials. The session will also review some considerations for persons who are applying to an NIH award that will involve human subjects, who are completing the Human Subjects and Clinical Trials Form.

Upon completion of this session, participants will be able to:

- Identify NIH policies pertaining to research involving human subjects
- Determine when research involving human subjects is a clinical trial
- Review considerations when applying for an NIH award for research that involves human subjects

Auditorium B / Track B - NIH Policies and Programs

Beyond Funding: NIH Support for Innovators

SEED's Innovator Support Team provides entrepreneurs with product development and business development guidance. Seasoned life science industry veterans and subject matter experts help innovators to strengthen the technical and business elements of their projects and prepare innovators for attracting investments or partnerships. These services, coupled with NIH product development funding, help innovators advance their discoveries from concept to clinic.

Upon completion of this session, participants will:

- know what services and expertise are available through SEED's Innovator Support Team;
- understand how to access SEED's Innovator Support Team; and
- understand how NIH support can strengthen the business elements of a product development project.

Auditorium C / Track C - Let's Talk About It

Intellectual Property: Understanding Requirements, Rights, and Recipient Responsibilities

The inventor is a [person] who looks around upon the world and is not contented with things as they are. He wants to improve whatever he sees, he wants to benefit the world; he is haunted by an idea. The spirit of invention possesses him, seeking materialization. Alexander Graham Bell (1891)

NIH-funded research can result in valuable inventions, patents, copyrights, data, and other resources. NIH experts will educate participants and assist in their understandings of these resources as they relate to NIH research funding and to advance research in your field for benefits to the public and public health throughout the world.

- explain basic concepts and definitions as they relate to inventions, copyrights, patents, data, and the Bayh-Dole Act and its compliance requirements; and
- describe basic Bayh-Dole reporting requirements including Invention Reports, Confirmatory Licenses, Government Support Clauses, and Utilization Reports.

4:00pm - 4:45pm EDT

Auditorium A / Track A - NIH Grants Process

Including Diverse Populations in NIH-funded Clinical Research

This session will provide an overview of NIH policies and procedures regarding the inclusion of women, minorities, and individuals across the lifespan. The session will include tips and interactive case studies to help NIH applicants write successful inclusion plans.

Upon completion of this session, participants will be able to:

- describe requirements for considering the inclusion of women, minorities, and individuals across the lifespan in NIH grant applications;
- apply strategies for developing realistic and scientifically acceptable inclusion plans; and
- understand requirements for post-award monitoring of inclusion of individuals in NIH clinical research studies.

Auditorium B / Track B - NIH Policies and Programs

Innovators in Action: Case Studies

Attendees will hear from a panel of individuals who have utilized NIH Small Business Program funding and support to develop and commercialize their technologies. Panelists will share their insights on locating the right small business funding opportunity, drafting a winning application, what to do after you receive the award, and building a fundamentally sound business foundation to ensure success of the company. Take advantage of the tips shared by these panelists about their up-and-down experiences transitioning technologies from the laboratory to the market.

Auditorium C / Track C - Let's Talk About It

Invention Reporting Under Bayh-Dole

Coming Soon

Visit the On-Demand Library of videos and descriptions in Auditorium D throughout the seminar.

Thank you for joining us!

Let us know how you liked the seminar by completing the evaluation under the feedback link in the top navigation pane of the seminar site.

Seminar resources will be available within the <u>conference platform</u> until November, 19, 2020. Anyone not already registered for this seminar may do so between Oct 31 and Nov 19, 2020 to access this material.

