CASE WESTERN RESERVE UNIVERSITY
SCHOOL OF DENTAL MEDICINE

News for the School of Dental Medicine Research Community

February 2017

Distributed via email on February 10th, 2017

Contents:

Any questions or comments about the information contained in this newsletter can be directed to dentres@case.edu.

NIH- Grants Podcasts

Designed for investigators, fellows, students, research administrators, and others, the podcasts provide insights on a variety of topics. The podcasts are in mp3 and updated every other week on the NIH OER site: http://grants.nih.gov/podcasts/All_About_Grants/index.htm

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On Campus Seminars

https://research.case.edu/researchapps/education/onlinecalendar.cfm

Date/Time of Event	Title/Description	Credits	Location	
2/14/2017 9:00 - 10:30 AM	***Recruitment Workshop: Strategies for Successful Study Enrollment*** Did you know that nationally nearly half of study sites fail to meet their enrollment target? Approximately 10% of sites don't enroll a single study participant! Join us at this workshop to learn the top barriers to successful study enrollment and how to overcome them.	4	UH Lakeside, Room 1400	Register
2/15/2017 11:00 - 1:00 PM	***IRB Walk-In Hours*** Do you have questions about the IRB review process? Do you need help getting started in iRIS? The UH Clinical Research Center can help!	0	UH Lakeside, Room 1400	Register
2/16/2017 11:30 - 1:00 PM	***IRB: Continuing Review Application or Study Closure*** Do you have questions about what is required to be submitted to the IRB for your continuing review (CR) or closure? Presented by IRB	3	UH Lakeside, Room 1400	Register

	Staff			
2/17/2017 8:30 - 4:30 PM	***Clinical Research Orientation*** Clinical Research Orientation is required for staff new to conducting clinical research at University Hospitals.	6	UH Bolwell Conference Room A	Register
2/21/2017 9:00 - 10:30 AM	***The Basics- An Education Series for Researchers: Module 6, Coverage Analysis & Research Billing Compliance*** Attendees will receive an overview of the entire billing process from patient registration through claim resolution and will learn about the positive impact coverage analysis has on study budgets and in streamlining the charge reconciliation process. Topics will include: research patient scheduling; required UH Clinical Trials notification; utilization of the shared drive for patient study lists and coverage analysis; and billing through Oncore.	2	UH Lakeside, Room 1400	Register
2/22/2017 2:00 - 4:00 PM	***IRB Walk-In Hours*** Do you have questions about the IRB review process? Do you need help getting started in iRIS? The UH Clinical Research Center can help!	0	UH Lakeside, Room 1400	Register
2/23/2017 9:00 - 10:30 AM	***How to Build a Questionnaire or Survey in REDCap (Research Electronic Data Capture)*** Come learn how to build a questionnaire and/or survey in UH! REDCap (Research Electronic Data Capture). This database software is a secure web application for building and managing online surveys/questionnaires and databases. REDCap provides audit trails for tracking data manipulation and user activity, as well as automated export procedures for seamless data downloads to Excel, PDF, and common statistical packages (SPSS, SAS, Stata).	0	UH Lakeside, Room 1400	Register
2/23/2017 2:00 - 3:00 PM	***UH Research SOP Training: QA 502 & QA 503*** This session will provide formal training on UH Clinical Research Standard Operating Procedures (SOPs). This will ensure applicable clinical research staff has an understanding of the requirements of the SOPs and the activities necessary for adherence to the following SOPs: QA 502: Monitoring Visits QA 503: Corrective and Preventative Action	0	UH Lakeside, Room 1400	Register
2/24/2017 11:30 - 1:00 PM	***IRB: Exempt Determination*** Federal regulations allow certain research activities involving human subjects to be exempt from IRB full or expedited review. Presented by the UH IRB. This session discusses: Types of IRB Review IRB Determination of Exempt Review Case Studies	0	UH Lakeside, Room 1400	Register
2/28/2017 9:00 - 10:00 AM	***Informed Consent and the Decisionally Impaired Human Subject Participant*** In this presentation, we will detail the intricacies associated with consenting decisionally impaired human subject research participants. Different types of impairment will be highlighted as well as the legal implications of research with this population. Presented by Dr. Barbara Daly, PhD, RN, Vice Chair, UHCMC IRB, Professor, CWRU, Director, Clinical Ethics, UHCMC	3	UH Lerner Tower, Room 2060	Register
3/2/2017 11:30	***The Basics- An Education Series for Researchers, MODULE 7, Adverse Events and Protocol Deviations***	4	UH Lakeside,	Register

- 1:00 PM	To define the process of Adverse Event collection and reporting definitions, policies and procedures at Seidman Cancer Center Clinical Trials Unit along with UH IRB Policies.		Room 1400	
3/3/2017 11:00 - 1:00 PM	***IRB Walk-In Hours*** DoDo you have questions about the IRB review process? Do you need help getting started in iRIS? The UH Clinical Research Center can help!	0	UH Lakeside, Room 1400	Register
3/7/2017 9:00 - 10:30 AM	***The Basics- An Education Series for Researchers, MODULE 8, FDA Regulations*** By the end of this module, you will learn and apply the following: □ Know the history of the Federal Regulations and ICH GCP □ How to identify the Code of Federal Regulations □ Understanding of the general content of the Code of Federal Regulations and ICH GCP Guidelines □ Understand the requirements of the Federal Regulations, Good Clinical Practice as it relates to FDA audits	3	UH Lakeside, Room 1400	Register
3/8/2017 2:00 - 4:00 PM	***IRB Walk-In Hours*** Do you have questions about the IRB review process? Do you need help getting started in iRIS? The UH Clinical Research Center can help!	0	UH Lakeside, Room 1400	Register
3/10/2017 10:00 - 11:30 AM	***Maintaining your IDE with the FDA: Keys for Success*** All investigators are invited to bring their staff to discuss the University Hospitals process for maintaining an investigator held Investigational Device Exemption (IDE) and will include: □ An investigator should prepare and submit an annual renewal to the FDA □ Items investigators need to include in the annual report to the FDA □ How to determine when a protocol amendment should be filed with the FDA □ Elements to be included in an amendment to the FDA □ Filing an FDA Med Watch Report: When required, where to send it, and how to complete it □ Tips and guidance on how to effectively respond to an FDA protocol inquiry □ Understanding the Investigator Agreement and Form FDA 3455 and successfully updating the forms □ Understanding FDA Guidance documents: How an investigator can keep their UH IRB and FDA approvals parallel and current	0	UH Lakeside, Room 1400	Register
3/13/2017 11:00 - 1:00 PM	***IRB Walk-In Hours*** Do you have questions about the IRB review process? Do you need help getting started in iRIS? The UH Clinical Research Center can help!	0	UH Lakeside, Room 1400	Register
3/14/2017 9:00 - 10:30 AM	***Study Visit Workshop 1: Study Start- Up*** During this interactive session, participants will learn what steps to take for a research study start-up. We will discuss study feasibility, take an in-depth look at a research protocol and steps for developing an informed consent form (ICF) and source document.	0	UH Lakeside, Room 1400	Register
3/16/2017 11:30 - 1:00 PM	***Recruitment Workshop: Strategies for Successful Study Enrollment*** Did you know that nationally nearly half of study sites fail to meet their enrollment target? Approximately 10% of sites don't enroll a	4	UH Lakeside, Room 1400	Register

	single study participant! Join us at this workshop to learn the top barriers to successful study enrollment and how to overcome them.			
3/20/2017 12:00 - 2:00 PM	***Informed Consent Workshop*** Join us during this interactive workshop covering the following: □ First Hour- Writing the document □ Second Hour-Consent a Subject. Please bring a copy of an IRB approved consent form from a study you are working on to the session	0	UH Lakeside, Room 1400	Register
3/21/2017 9:00 - 10:30 AM	***Study Visit Workshop 2: Mock Study Visit*** During this interactive session, participants will take an in-depth look at an example research protocol and participate in a mock patient visit for a practical look at what happens before, during and after a clinical research study visit. Participants will learn how to use a protocol, how to fill out source documents and how to identify and report adverse events.	0	UH Lakeside, Room 1400	Register
3/22/2017 2:00 - 4:00 PM	***IRB Walk-In Hours*** Do you have questions about the IRB review process? Do you need help getting started in iRIS? The UH Clinical Research Center can help!	0	UH Lakeside, Room 1400	Register
3/24/2017 11:30 - 1:00 PM	***The Basics: An Education Series for Researchers, MODULE 9- Avoiding Non-Compliance Findings*** We will review the top non-compliance findings and provide helpful tips and tools will be provided to help research teams prevent these significant findings.	3	UH Lakeside, Room 1400	Register
3/28/2017 9:00 - 10:30 AM	***Study Visit Workshop 3: Maintenance, Monitoring, and Closeout*** During this interactive session, participants will discuss how to handle protocol changes, research staff training, data management and query resolution. We will also take a look at preparing a study for closure including final study report, data cleaning, and publication.	0	UH Lakeside, Room 1400	Register
3/31/2017 10:00 - 11:00 AM	***What to do for an FDA Inspection*** In this presentation, you will understand why the FDA does site inspections, learn what an FDA site investigation entails and how to prepare, and lastly understand what results from the FDA site inspection.	0	UH Lakeside, Room 1400	Register
3/31/2017 11:00 - 1:00 PM	***IRB Walk-In Hours*** Do you have questions about the IRB review process? Do you need help getting started in iRIS? The UH Clinical Research Center can help!	0	UH Lakeside, Room 1400	Register
4/4/2017 9:30 - 10:30 AM	***Data Management Basics Series: Basic 1- It's a System!*** Talking through the critical questions, the march of science, systems and diagrams. Start here to understand the entire process.	0	CWRU SOM WG-86	Register
4/6/2017 11:30 - 1:00 PM	***The Basics- An Education Series for Researchers, MODULE 10- SEIDMAN CTSU (Cancer Trial Support Unit) and LPO (Lead Protocol Organization)*** This module will define the CTSU (Cancer Trial Support Unit) and National Clinical Trials Network Lead Protocol Organizations roles and our interaction as LAPS (Lead Academic Participating Site) members with each group.	0	UH Lakeside, Room 1400	Register

4/11/2017 9:30 - 10:30 AM	***Data Management Basic Series- Basic 2, Research Plan*** Learn the elements of a well-developed Research Plan including an Introduction, Background, Goals, Clinical Plan, Data management Plan, Statistical Analysis Plan, Regulatory Considerations Human Subject Protections.	0	CWRU SOM WG-86	Register
4/18/2017 9:30 - 10:30 AM	***Data Management Series, Basic 3- Building a Data Management Plan*** Outline the basic data management process and data flow. Examine the elements of a data management plan. Define individual roles, responsibilities, and access privileges.	0	CWRU SOM WG-86	Register
4/20/2017 11:30 - 1:00 PM	***The Basics- An Education Series for Researchers, MODULE 11- Oncore Training (CANCER CTU ONLY)*** Join us for a walkthrough in Oncore from study activation to study close out.	0	UH Lakeside, Room 1400	Register
4/21/2017 8:30 - 4:30 PM	***UH Clinical Research Orientation*** The Center for Clinical Research and Technology offers the Clinical Research Orientation program which is required for staff new to conducting clinical research at University Hospitals.	6	UH Bolwell Conference Room A	Register
4/25/2017 9:30 - 10:30 AM	***Data Management Series, Basic 4- Data Entry and Quality Control (including CRF design)*** Ensure the CRF reflects the protocol's main points. Develop clear unambiguous questions. Discuss the development of CRF instructions. Address common design challenges and design the CRF to record data that can be used in the final study report. Develop methods to track CRFs.	0	CWRU SOM WG-86	Register
4/28/2017 11:30 - 1:00 PM	***Submitting a Pre-IDE Application to the FDA*** This session is applicable for any investigator or research personnel who are unsure if the device they are working with or developing is classified as significant rick or non-significant risk. Learn the basics of submitting a Pre-IDE Application to the FDA, the differences between a significant risk vs. non significant risk device, and the nuances of device applications and submissions to the FDA.	0	UH Lakeside, Room 1400	Register
5/2/2017 9:30 - 10:30 AM	***Data Management Series, Advanced 1- The Regulations: HIPAA for Research*** Ensure data collection and management complies with HIPAA privacy laws. Review PHI and identifiers. Common Rule vs. Privacy Rule.	3	CWRU SOM WG-86	Register
5/4/2017 11:30 - 1:00 PM	***Investigator and Study Team Responsibilities*** Do you understand the responsibilities of an investigator when conducting clinical research? It is essential all members of the clinical research team, including the Principal Investigator, understand these responsibilities and also the appropriate delegation of these responsibilities to study staff. Plan to attend this informative session and learn from colleagues with numerous years of experience in conducting and managing clinical research. All Principal Investigators are encouraged to attend this session.	3	UH Lakeside, Room 1400	Register
5/9/2017 9:30 - 10:30 AM	***Data Management Series, Advanced 2- The Regulations: 21 CFR Part 11*** Scope and application guidance, electronic records, electronic signatures, and validation.	3	CWRU SOM WG-86	Register
5/12/2017 9:30 - 11:00 AM	***How do you know when an Investigational New Drug (IND) application is required?*** All investigators are invited to bring their staff to discuss the UHCMC process for obtaining an investigator held Investigational New Drug	0	UH Lakeside, Room 1400	Register

	(IND) Application			
5/16/2017 11:30 - 12:30 PM	***Data Management Series, Advanced 3- Data Safety Monitoring Board*** A system for the oversight and monitoring of the conduct of clinical trials to ensure the safety of participants and the validity and integrity of the data. The data and safety monitoring functions and oversight of study activities are distinct from the requirement for study review and approval by an Institutional Review Board (IRB).	3	CWRU SOM WG-86	Register
5/18/2017 11:30 - 1:00 PM	***IRB: Preparing a Successful Submission*** Are you preparing to submit to the UH IRB? This session provides the information to get started. We will review the IRB submission process and policy that covers all required elements and demonstrate how to complete one using iRIS. Presented by the UH IRB Staff	3	UH Lakeside, Room 1400	Register
5/23/2017 9:30 - 10:30 AM	***Data Management Seris, Advanced 4- Study Infrastructure Template*** A template to help organize the entire study.	3	CWRO SOM WG-82C	Register
5/26/2017 11:30 - 1:00 PM	***IRB: Amendments, & Revisions*** This session walks through the process of amending an approved study and revising and attaching documents in Iris. Presented by UH IRB Staff	0	UH Lakeside, Room 1400	Register
Summer 2017				
6/1/2017 11:30 - 1:00 PM	***IRB: Continuing Review Application or Study Closure*** This program will include an in-depth review of the elements required for both continuing review and study closure submissions. Tips for preventing a lapse in IRB approval will be discussed.	3	UH Lakeside, Room 1400	Register
6/6/2017 9:00 - 10:30 AM	***Informed Consent Workshop*** Join us during this interactive workshop covering the following: □ First Hour- Writing the document □ Second Hour-Consent a Subject. Please bring a copy of an IRB approved consent form from a study you are working on to the session	0	UH Lakeside, Room 1400	Register
6/9/2017 9:30 - 11:00 AM	***FDA Guidance Core Lecture Series: Application Essentials: Pre-IND and Full IND Application*** Investigators are invited to bring their staff to discuss what essentials are needed for a Pre-IND and the Full IND application	3	UH Lakeside, Room 1400	Register
6/15/2017 11:30 - 1:00 PM	***IRB: Exempt Determination*** Federal regulations allow certain research activities involving human subjects to be exempt from IRB full or expedited review. Presented by the UH IRB. This session discusses: □ Types of IRB Review □ IRB Determination of Exempt Review □ Case Studies	0	UH Lakeside, Room 1400	Register
6/20/2017 9:00 - 10:30 AM	***The Basics- An Education Series for Researchers: Module 1, Regulatory Binder and Essential Documents*** During this session, we will define essential regulatory documents and discuss what your regulatory binder should contain. Bring your "reg binder" to the session and we can help you identify missing information or help you get started in putting one together.	3	UH Lakeside, Room 1400	Register

6/22/2017 8:30 - 4:30 PM	***Clinical Research Orientation*** The Center for Clinical Research and Technology offers the Clinical Research Orientation program which is required for staff new to conducting clinical research at University Hospitals.	6	UH Bolwell Conference Room A	Register
6/27/2017 9:00 - 10:30 AM	***The Basics- An Education Series for Researchers: MODULE 2- Study Activation*** This module will define protocol development and activation, its guiding principles, the document, and overall process for obtaining at University Hospitals.	0	UH Lakeside, Room 1400	Register
7/6/2017 11:30 - 1:00 PM	***The Basics- An Education Series for Researchers: Module 3 - Prescreening, eligiblity and enrollment*** This module will define the process of pre-screening, eligibility review and verification and enrollment for subjects enrolled at University Hospitals.	3	UH Lakeside, Room 1400	Register
7/11/2017 9:00 - 10:30 AM	***The Basics- An Education Series for Researchers: MODULE 4, Informed Consent & Reconsent*** This presentation will help to define the guiding principles of the informed consent process, forms used during process and documentation of re-consent.	4	UH Lakeside, Room 1400	Register
7/14/2017 9:30 - 11:00 AM	***Maintaining your IND and Investigator Brochure with the FDA*** All investigators are invited to bring their staff to discuss the UHCMC process for maintaining an investigator held Investigational New Drug (IND) Application and Investigator Brochure. Topics of discussion include, how an investigator should prepare and submit an annual renewal to the FDA; items investigators need to include in the annual report to the FDA; how to determine when a protocol amendment should be filed with the FDA; tips and guidance on how to effectively respond to an FDA protocol inquiry.	0	UH Lakeside, Room 1400	Register
7/18/2017 9:00 - 10:30 AM	***Study Visit Workshop 1: Study Start- Up*** During this interactive session, participants will learn what steps to take for a research study start-up. We will discuss study feasibility, take an in-depth look at a research protocol and steps for developing an informed consent form (ICF) and source document.	0	UH Lakeside, Room 1400	Register
7/25/2017 9:00 - 10:30 AM	***Study Visit Workshop 2: Mock Study Visit*** During this interactive session, participants will take an in-depth look at an example research protocol and participate in a mock patient visit for a practical look at what happens before, during and after a clinical research study visit. Participants will learn how to use a protocol, how to fill out source documents and how to identify and report adverse events.	0	UH Lakeside, Room 1400	Register
7/28/2017 11:30 - 1:00 PM	***The Basics- An Education Series for Researchers: MODULE 5, Research Documentation and Data Management*** Documentation in clinical practice is essential for communication among healthcare providers. It is from this documentation that protocol-specific data is abstracted, submitted and analyzed. Clinical data management consists of various activities involving the handling of information that is outlined in the protocol to be collected / analyzed. These activities lead to the generation of high-quality, reliable and statistically sound clinical trial data.	3	UH Lakeside, Room 1400	Register
8/1/2017 9:00 - 10:30 AM	***Study Visit Workshop 3: Maintenance, Monitoring, and Closeout*** During this interactive session, participants will discuss how to handle protocol changes, research staff training, data management and query resolution. We will also take a look at preparing a study for	0	UH Lakeside, Room 1400	Register

	closure including final study report, data cleaning, and publication.			
8/8/2017 9:00 - 10:30 AM	***The Basics- An Education Series for Researchers: Module 6, Coverage Analysis & Research Billing Compliance*** Attendees will receive an overview of the entire billing process from patient registration through claim resolution and will learn about the positive impact coverage analysis has on study budgets and in streamlining the charge reconciliation process. Topics will include: research patient scheduling; required UH Center for Clinical Research & Technology notification; utilization of the shared drive for patient study lists and coverage analysis; and billing through Oncore.	2	UH Lakeside, Room 1400	Register
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8/11/2017 9:30 - 11:00 AM	***Dietary Supplements and Vitamins: When is FDA Regulation Necessary?*** This session provide information on the FDA's regulatory oversight of dietary supplements and Vitamins, discuss in detail the reasons that would require an FDA review of a supplement or vitamin protocol, and the most effective regulatory pathway with the FDA should their review be required.	0	UH Lakeside, Room 1400	Register
8/15/2017 9:00 - 10:30 AM	***The Basics- An Education Series for Researchers, MODULE 7, Adverse Events and Protocol Deviations*** To define the process of Adverse Event collection and reporting definitions, policies and procedures at Seidman Cancer Center Clinical Trials Unit along with UH IRB Policies.	4	UH Lakeside, Room 1400	Register
8/17/2017 11:30 - 1:00 PM	***Investigator and Study Team Responsibilities*** Do you understand the responsibilities of an investigator when conducting clinical research? It is essential all members of the clinical research team, including the Principal Investigator, understand these responsibilities and also the appropriate delegation of these responsibilities to study staff. Plan to attend this informative session and learn from colleagues with numerous years of experience in conducting and managing clinical research. All Principal Investigators are encouraged to attend this session.	3	UH Lakeside, Room 1400	Register

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Grant Submission Process

- **Inform people**

When a Principal Investigators (PI's) is planning to submit a grant application they are required to inform their Department Chairman, Matt Fletcher the SoDM's Director of Research Administrator (DRA) and their Department Administrator (DA) at least 3 weeks before the grant is due. This keeps people informed of PI's additional efforts and possible difficulties that may occur due to the submission that the PI may not be aware of.

- **Enter into Sparta**

Once the PI has documents ready to submit to the Sponsor it is required by the SoDM that all applications be entered into the University's grant management system called SPARTA (short for Sponsored Programs Application for Research Tracking + Administration). SPARTA is used for the submission of grant proposals, initiation of research contracts, management of active grants and contracts (reporting) and closing grants and research contracts. The DA will enter the application information into SPARTA and route the application within SPARTA for approval.

- **Routing**

There are 5 signatures required for most submission in SPARTA: PI, DA, Dept. Chair, Management Center, and Office of Technology and Management (ORTM). If the application is received by the ORTM 5 days before it is

due the ORTM will review the grant information (mostly budget information) and submit the application with the ability to resend information if errors occur on 1st attempt. The later an application is received by the ORTM the lower the chances the application can be resent if errors exist (don't wait until the hour before it's due to send it the 1st time). In cases where PI's can submit/route applications directly to the Sponsor without a Signing Official (SO) of the University's approval the PI is allowed to submit directly at any time on their own but must inform the required individuals within the SoDM so the application can be entered into SPARTA. All NIH grants require a SO to send applications.

- **Confirmation**

Once the Application has been submitted it should be confirmed by the PI and DRA that the Sponsor has received the application and that it is error free. If an error exists the application can usually be withdrawn, corrected and recent to the Sponsor, provided there is a reasonable amount of time to do so.

At the Veale Convocation Center

Submit your abstract now!
http://showcase.case.edu

Abstract submission deadline: Sunday, February 20, 2017
(for graduate and professional students, faculty, staff and affiliates)
Undergraduate submissions for Intersections will begin in mid-February, deadline is March 26

We invite you to participate with other CWRU faculty, staff and students by presenting your work at Research ShowCASE 2017. The event will provide an opportunity for CWRU researchers to display your research in a traditional scientific poster or other creative means. We encourage University Hospitals, Cleveland Clinic, MetroHealth Medical Center and the Louis Stokes Cleveland VA Medical Center researchers to participate.

In addition to the opportunity to display and share your work, undergraduate and graduate students, professional students and postdoctoral scholars are encouraged to participate in the research competition, which will include having your presentation evaluated and feedback provided. Cash prizes will be awarded to winning entries.

In order to display your work at Research ShowCASE, you will need to submit an online abstract describing your research. If you are a student or post-doc, your faculty adviser will need to approve your submission.

NIH News Letter- Updates to eRA Commons- February 2017

The NIH started the transition to the Research Performance Progress Report (RPPR) back in April of 2012. And now, with NIH having transitioned to the Final RPPR as of January 1, 2017, they have one more transition to make which will be the Interim RPPR.

The Interim RPPR (IRPPR) will be used when a PI is submitting a Competing Renewal application (Type 2). Since the Type 2 application is a competing application, there is no guarantee it will be awarded. And whether it is or isn't awarded, can create some confusion about what to do for a final report.

So here is the scenario of how the Interim RPPR will be used. If you opt NOT to apply for Competing Renewal, complete the Final RPPR as you normally would within 120 days of the project end date. If you are going to complete a Competing Renewal application (or have already submitted such an application), you will submit an Interim RPPR. This must be submitted within 120 days of the project end date.

If you are awarded the renewal, the Interim RPPR will be treated as your annual RPPR and no other progress reporting will be needed for that segment of the study. If the application is NOT awarded, then the Interim RPPR will be accepted as the Final RPPR.

Who can initiate and submit these various types of RPPRs?
First, annual RPPRs have not changed at all. The Progress Report delegation permits any user with the ASST role the ability to complete progress report information for a specified PI, but they cannot route or submit the report. The Submit delegation permits a specified Principal Investigator (PI) the ability to submit to agency the progress report, listing them as the Signing Official (SO) for that submission.

Second, Interim and Final RPPR work in the same manner as the old Final Progress Report (FPR). With the FPR, both SOs and PIs could initiate and/or submit to agency. They could also route the report back and forth for review and edits. All of this done without the need to delegate any authority. Interim RPPR and Final RPPR work in the same manner. No delegations needed for the initiation and submission of either version of these RPPRs.

Now because the format between the annual RPPR, the Interim RPPR and the Final RPPR are so similar, and permissions and delegations have not changed, this transition will be no tribble at all! (Come on! You *knew* I was goin' there!)

Another change is soon University Signing Officials (SO) will be able to request an NCE electronically through eRA Commons via Prior Approval. A PI will be able to go to the *Prior Approval* tab in eRA Commons, and from the Initiate a *Prior Approval Request* box, select No Cost Extension from the drop down and click **Go**. The eRA Commons will find and display a list of eligible grants. Find and select the desired grant and click the **Initiate No Cost Extension** button. Complete the request form, supplying the requested information.

When is a grant eligible for a NCE through Prior Approval?
- When you have already used a NCE under expanded authority and you are within 90 days of the project end date.
- When you are not under expanded authority and you are within 90 days of the project end date.
- When the project end date has expired and has not been closed or has not entered unilateral closeout, whichever comes first.

When is a grant NOT eligible for a NCE through Prior Approval?
- When you have never requested a NCE under expanded authority and you are within 90 days of the project end date. In this case, the NCE will be processed normally through the **Extension** link in *Status*.
- When the grant is closed.
- When the grant is a fellowship grant.

What information will you need to provide?
- The NCE request form consists of 4 sections:
  - Request Detail – Here you will be asked such things as the number of months you wish to extend the project end date; the amount of unobligated money still available, etc.
  - Three PDF upload fields: Progress Report, Budget Document, Justification Document

The exact details of what will be needed in these uploaded files will be outlined by the awarding IC.

The goals here are to standardize the process; provide tracking and accountability for requests; and leverage existing data by working through eRA Commons.

Prior Approval Changes How PIs Change

Along with the new NCE option in Prior Approval, the NIH is also introducing the ability to request a Change of PD/PI or adding/deleting multiple PIs through Prior Approval.

As sometimes happens, institutions need to replace a previously approved Program Director or Principal Investigator (PD/PI) with an individual that is approved by the awarding Institute or Center (IC). This process, starting in late February can be initiated and managed through eRA Commons.

Only a Signing Official (SO) can initiate the request. Principal Investigators cannot see Change of PD/PI Requests. The SO logs into eRA Commons; goes to the *Prior Approval*tab; from the *Initiate a Prior Approval Request* box; selects Change of PD/PI Request from the drop down; and then clicks **Go**.

The system will present a list of eligible grants. The following conditions must be met for a grant to be eligible for a Change of PD/PI Request:

- The grant has a grant year awarded.
- The grant family is not past the Project Period End Date.
- The grant is not a Fellowship or Career.
- The grant is from an IC/Agency that supports Change of PD/PI using the Prior Approval module.

When a grant is selected from the list, an **Initiate Change of PD/PI** button is made available. Clicking the button opens the Prior Approval Request Change of PD/PI form. The details for the request require some basic information:

- Who is being replaced, removed/added to the grant?
- What will their level of effort be?
- What is the effective start date for the new PD/PI?

Additionally, some files will be uploaded to be attached to the request.

- Biosketch
- Other Support
- Justification Document

Of course, as with other prior approval requests, working with the Grants Management Specialist of the awarding Institute or Center will be important to know what information will be required for the request.

Once the request is submitted, the system creates a PDF of all the submitted information and sends a notification to the SO, the GMS, and Program Officer so they can review the request.

Joe Schumaker
eRA Communications
Division of Communications and Outreach
NIH Office of Extramural Research

Tip of the Month

- OSPA now ORTM and new Contacts for the SODM

As you know, virtually everything that gets submitted to a sponsor requires the sign-off of an authorized University official. In the past, this office was called the Office of Sponsored Projects and Administration (OSPA) but in early 2016 they changed their name to the Office of Research and Technology Management (ORTM) At around this time ORTM Joy Dismukes, was hired as the new Assistant Director in ORTM, who is the primary contact for the SODM. Joy came from the Case's School of Medicine's Grants and Contracts Office, where she has held various positions within the research office for the past 3 years. Please feel free to contact Joy with any issues. She can be reached at 368-2009 or jmd219@case.edu.

- PMCID's and their importance

A PMID, also known as the PubMed reference number, is a number assigned by the NIH National Library of Medicine to papers indexed in PubMed. The PMC reference number (PMCID) is assigned when the article is

posted on PubMed Central. It is the proof of compliance that you must include when submitting applications, proposals, and reports to the NIH.

Do I have to include a PMCID for every paper that I cite in an NIH application, proposal or progress report?
Yes, include the PMCID if the paper is:
1. Authored by you or arose from your NIH funds (even if you are not an author); **and**
2. Is covered by the Public Access Policy (see http://publicaccess.nih.gov/determine_applicability.htm.)

List of Funding Opportunities

The Office of Research and Technology Management (ORTM) used to provide a running list of funding opportunities but awhile back they choose to allow members of the Case Western Community to perform their own searches through a University membership to PIVOT, a database of funding opportunities compiled from multiple agencies (https://pivot.cos.com/session/login).

Attached below are some opportunities that maybe of interest to the School of Dental Medicine community. While every effort is made to ensure the deadline dates shown are correct, please consult the program website to confirm application due dates are correct.

Title	Deadline	Amount
Dissemination and Implementation Research in Health (R21) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	3/16/17	$275,000USD
Systems Science and Health in the Behavioral and Social Sciences (R21) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	2/16/17	$275,000USD
Dissemination and Implementation Research in Health (R03) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	3/16/17	$100,000USD
NIDCR Behavioral or Social Intervention Clinical Trial Planning Grant (R34) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH) National Institute of Dental and Craniofacial Research (NIDCR)	2/16/17	$150,000USD
Basic Research on HIV Persistence (R21) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	9/7/17	$275,000USD
Emerging Global Leader Award (K43) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	12/14/17	$105,000USD
Administrative Supplements for Research on Dietary Supplements (Admin Supp) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	4/15/17	$100,000USD
Academic Research Enhancement Award (Parent R15) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	2/25/17	$300,000USD
Early Stage Development of Technologies in Biomedical Computing, Informatics, and Big Data Science (R01) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	3/5/17	$900,000USD

Small Research Grants for Establishing Basic Science-Clinical Collaborations to Understand Structural Birth Defects (R03) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	2/16/17	$75,000USD
Postdoctoral Research Fellowships in Biology (PRFB) National Science Foundation (NSF) Directorate for Biological Sciences (BIO)	11/1/17	$207,000USD
Opportunities for Collaborative Research at the NIH Clinical Center (U01) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	4/11/17	$500,000USD
NSF Astronomy and Astrophysics Postdoctoral Fellowships (AAPF) National Science Foundation (NSF) Directorate for Mathematical and Physical Sciences (MPS) Division of Astronomical Sciences (AST)	10/12/17	$267,000USD
Small Research Grants for Analyses of Data for the Gabriella Miller Kids First Data Resource (R03) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	2/16/17	$200,000USD
Early Career Fellowships Australian Government Department of Health - Australia National Health and Medical Research Council (NHMRC) - Australia	3/1/17	$318,768AUD
PCORI Funding Announcement: Pragmatic Clinical Studies to Evaluate Patient-Centered Outcomes Patient-Centered Outcomes Research Institute (PCORI)	2/14/17	$10,000,000USD
IADR/GlaxoSmithKline Innovation in Oral Care Awards International Association for Dental Research (IADR)	12/9/17	$75,000USD
IADR/Academy of Osseointegration Innovation in Implant Sciences Award International Association for Dental Research (IADR)	12/9/17	$75,000USD
Tailoring Dental Treatment for Individuals With Systemic Diseases That Compromise Oral Health (R21) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH) National Institute of Dental and Craniofacial Research (NIDCR)	2/16/17	$275,000USD
Tailoring Dental Treatment for Individuals With Systemic Diseases That Compromise Oral Health (R01) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH) National Institute of Dental and Craniofacial Research (NIDCR)	3/5/17	$275,000USD
Immune System Plasticity in the Pathogenesis and Treatment of Complex Dental, Oral, and Craniofacial Diseases (R21) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH) National Institute of Dental and Craniofacial Research (NIDCR)	2/16/17	$275,000USD
NIDCR Small Research Grants for Data Analysis and Statistical Methodology Applied to Genome-Wide Data (R03) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH) National Institute of Dental and Craniofacial Research (NIDCR)	2/16/17	$200,000USD
Establishing Behavioral and Social Measures for Causal Pathway Research in	5/7/17	$200,000USD

Dental, Oral and Craniofacial Health (R21) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH) National Institute of Dental and Craniofacial Research (NIDCR)		
Factors Underlying Differences in Female and Male Presentation for Dental, Oral, and Craniofacial Diseases and Conditions (R21) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	2/16/17	$200,000USD
NIDCR Small Grant Program for New Investigators (R03) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH) National Institute of Dental and Craniofacial Research (NIDCR)	2/16/17	$100,000USD
Research Grants Shwachman-Diamond Syndrome Foundation (SDSF)	5/15/17	$70,000USD
ICR Clinical Surgery Fellowship Oral and Maxillofacial Surgery Foundation (OMSF)	7/15/17	$70,000USD
Health of Sexual and Gender Minority (SGM) Populations (R21) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	2/16/17	$100,000USD
NIDCR Small Research Grants for Oral Health Data Analysis and Statistical Methodology Development (R03) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH) National Institute of Dental and Craniofacial Research (NIDCR)	2/16/17	$200,000USD
NIDCR Small Research Grants for Secondary Analysis of FaceBase Data (R03) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH) National Institute of Dental and Craniofacial Research (NIDCR)	2/16/17	$200,000USD
Population Health Interventions: Integrating Individual and Group Level Evidence (R21) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	2/16/17	$200,000USD
Zika Virus (ZIKV) Complications (R21) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	2/16/17	$200,000USD
NIDCR Clinical Trial or Biomarker Clinical Validation Study Planning Grant (R34) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH) National Institute of Dental and Craniofacial Research (NIDCR)	2/16/17	$150,000USD
In-Depth Phenotyping and Research Using IMPC-Generated Knockout Mouse Strains Exhibiting Embryonic or Perinatal Lethality or Subviability (R01) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	6/5/17	$499,999USD
Improvement of Animal Models for Stem Cell-Based Regenerative Medicine (R21) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	2/16/17	$275,000USD
Research on Chronic Overlapping Pain Conditions (R21) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	2/16/17	$275,000USD

Biology of the Temporomandibular Joint in Health and Disease (R21) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	2/16/17	$275,000USD
Neurobiology of Migraine (R21) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	2/16/17	$275,000USD
Exploratory/Developmental Bioengineering Research Grants (EBRG) [R21] United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	2/16/17	$275,000USD
High or Medium Priority AIDS Research on Non-AIDS-Defining or AIDS-Defining Cancers (R21) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	5/7/17	$200,000USD
NIH Exploratory/Developmental Research Grant Program (Parent R21) United States Department of Health and Human Services (HHS) National Institutes of Health (NIH)	2/16/17	$275,000USD

William T. Grant Foundation - William T. Grant Scholars Program

Key Deadlines: *March 21, 2017 by 5:00pm EST (CWRU internal letter of intent to research dean); July 6, 2017 by 3:00pm EST (Sponsor's ANTICIPATED proposal deadline). The foundation has not yet released the 2017 RFP.*

The William T. Grant Scholars Program is for early-career researchers in the social, behavioral, and health sciences. We encourage Scholars to tackle important questions that will advance theory, policy, and practice for youth. Applicants identify new methods, disciplines, or content they want to learn, and propose five-year research plans that foster their growth in those areas. The foundation recognizes that early-career researchers are rarely given incentives or support to take such risks, so this award includes a mentoring component. Potential Scholars should have a promising track record of conducting high-quality research, but want to pursue a significant shift in their trajectories as researchers. Award recipients are designated as William T. Grant Scholars. Each year, four to six Scholars are selected and each receives up to $350,000, distributed over five years. Awards begin July 1 and are made to the applicant's institution. The award must not replace the institution's current support of the applicant's research.

The foundation is focused on youth ages 5 to 25 in the United States. The foundation funds research that increases our understanding of: programs, policies, and practices that reduce inequality in youth outcomes, and strategies to improve the use of research evidence in ways that benefit youth.

The foundation seeks research that builds stronger theory and empirical evidence in these two areas. The foundation intends for the research it supports to inform change. While it is not expected that any one study will create that change, the research should contribute to a body of useful knowledge to improve the lives of young people.

Number of Applications Allowed: One
Amount of Funding: $350,000, payable over five years
Program Website: http://wtgrantfoundation.org/Grants#apply-wtgrant-scholars

Edward Mallinckrodt, Jr. Foundation: Mallinckrodt Grants Applications

Key Deadlines: April 21, 2017, 5:00pm (CWRU Letter of Intent), August 1, 2017, 5:00pm EST (external application).

The Edward Mallinckrodt, Jr. Foundation is a private foundation that funds basic biomedical research in St Louis and throughout the United States.

Mallinckrodt Grants are competitively provided to investigators based on their proposals, selected from applicants on an annual basis. These awards are usually $60,000 per year for three years, provided an annual progress report is submitted and approved.

Number of Applications Allowed: **One**
The official announcement and description of this opportunity may be found on the foundation's website, here.

Kinship Foundation - The Searle Scholars Program

Key Deadlines: June 20, 2017, 5:00pm (CWRU internal application), September 29, 2017 (Sponsor's ANTICIPATED proposal

deadline). Nominations should open June 1, 2017.

Case Western Reserve University is invited to submit applications for the 2018 Searle Scholar Program competition.

The Searle Scholars Program supports research of outstanding individuals who have recently begun their appointment at the assistant professor level, and whose appointment is their first tenure-track position at a participating academic or research institution. Today, 153 institutions are invited to participate in the Program.

The Program was established at The Chicago Community Trust in 1980 and has been administered by Kinship Foundation since 1996. The Program is funded from the estates of Mr. and Mrs. John G. Searle. Mr. Searle was the grandson of the founder of the world-wide pharmaceutical company, G.D. Searle & Company. It was Mr. Searle's wish that certain funds be used to support "...research in medicine, chemistry, and the biological sciences."

Each year 15 new individuals are named Searle Scholars. Awards are currently set at $100,000 per year for three years. Since its inception, 527 Scholars have been named and over $111 million has been awarded.

Number of Applications Allowed: Two
Amount of Funding: $300,000 ($100,000 per year for three years)
Program Website: http://www.searlescholars.net/

Additional Sources:
HRSA
ADA
ADDR
GSK
B&M Gates Foundation
Keck Foundation