

Office of Research Services Professional Development Series 2015 (subject to change)
PRESENTATION DESCRIPTIONS

Grants.gov (1.5 hours)

This presentation provides a “soup to nuts” overview of what Grants.gov is, and how it works in the context of making grant applications to federal agencies.

Primary Target Audience: Investigators (all levels), Business Managers, Assistant Business Managers, and Coordinators

At the conclusion of this activity, the learner should be better able to:

1. Navigate Grants.gov and eRA Commons in order to find, apply for, and review completed applications for federal grant funding.
2. Coordinate with the Office of Research Services to ensure appropriate grant application processing.
3. Avoid common errors and pitfalls associated with electronic grant application submission.

NIH Application Forms (1.5 hours)

A tour of a “typical” NIH grant application will be conducted, with instructions for completing each section provided. Emphasis will be placed on avoiding common errors.

Primary Target Audience: Investigators (all levels), Business Managers, Assistant Business Managers, and Coordinators

At the conclusion of this activity, the learner should be better able to:

1. Recognize recent changes to NIH grant application form and content.
2. Submit federal grant applications which are in line with NIH updated review criteria and page limits.
3. Prepare each element of a "typical" NIH grant application, including the face page, research plan, cover page supplement, senior/key personnel, other project information, project/performance site location, budget, planned enrollment, and subaward information.

Tips for Beginning Investigators (1.5 hours)

New and early stage investigators will benefit from this presentation, which includes not only an overview of appropriate NIH award mechanisms, but also information on resources available to all investigators (Grants.gov, the LA BoR listserv, IRIS, etc.)

Primary Target Audience: New and Early-Stage Investigators, Postdocs, Fellows, Business Managers, Assistant Business Managers, and Coordinators

At the conclusion of this activity, the learner should be better able to:

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1. Locate useful grant-related training and information resources and sign up for various listservs.
2. Select an appropriate funding source (federal, state, or private) and funding mechanism.
3. Internalize LSUHSC-NO's policies and procedures regarding grant submissions.

Grant Application Writing (1.5 hours)

Developing effective grant writing skills is essential to acquire competitive funding from government agencies and private foundations. Writing a successful grant proposal is a blend of art and science. It requires basic knowhow, content knowledge, writing proficiency, strong research skills, creativity, organizational ability, patience, and a great deal of luck. This session will provide participants with the background necessary to develop a competitive funding proposal. This session will be presented by a panel of experienced, successful NIH-funded Principal Investigators.

Primary Target Audience: Investigators (all levels), Business Managers, Assistant Business Managers, and Coordinators

At the conclusion of this activity, the learner should be better able to:

1. Develop a compelling grant application with an emphasis on a strong hypothesis and achievable aims.
2. Edit judiciously while communicating complex scientific concepts.
3. Respond constructively, via application resubmission, to peer review comments.

Using eRA Commons (1.5 hours)

This presentation will provide an overview of Commons functionality, including requesting that an account be established, setting up a profile, delegating task authority to others, and submission of just-in-time information, final reports/closeouts, invention statements, and relinquishing statements. We will also touch on performing Internet-assisted reviews, managing training grants via xTrain, changing institutions, and preparing an application for an administrative supplement.

Primary Target Audience: Investigators (all levels), Business Managers, Assistant Business Managers, Coordinators, and anyone who has been delegated an investigator's authority to use Commons

At the conclusion of this activity, the learner should be better able to:

1. Arrange for establishment of an eRA Commons account.
2. Navigate within eRA Commons, including logging in, delegating authority, creating a personal profile, tracking grant applications, submitting information, closing out grants, and performing reviews.
3. Electronically route items for review, approval, and submission to the NIH.

Conducting a Medicare Coverage Analysis for Clinical Trials (1.5 hours)

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To ensure appropriate reimbursement for the services provided to a patient in a clinical trial, research sites must develop a budget for each trial. One important step in developing a clinical trial budget is conducting a Medicare Coverage Analysis, sometimes referred to as an MCA. This identifies the services for which Medicare will pay under the Medicare Clinical Trial Policy. A methodical analysis helps avoid compliance pitfalls with regard to inappropriate billing, while ensuring that all LSUHSC-NO costs associated with conducting the trial are covered.

Primary Target Audience: Clinical Researchers, Research Coordinators, Nurses, Business Managers, and Assistant Business Managers

At the conclusion of this activity, the learner should be better able to:

1. Determine whether a specific clinical trial qualifies for Medicare coverage.
2. Understand the difference between therapeutic intent versus testing, standard of care versus conventional care, and routine costs versus research costs.
3. Perform a detailed review of the clinical events specified in the protocol to determine which can be reimbursed.

Preparing Budgets for Grant Applications and Clinical Trial Agreements (1.5 hours)

Thoughtful preparation of a grant or clinical trial budget on the front end leads to ease in management on the back end. With that goal in mind, this presentation will focus on use of the ORS budget template, issues surrounding F&A cost recovery, cost sharing, and more.

Primary Target Audience: Investigators (all levels), Business Managers, Assistant Business Managers, and Coordinators

At the conclusion of this activity, the learner should be better able to:

1. Identify and calculate key components of a grant/clinical trial budget, including personnel, supplies, consultants, travel, other expenses, patient compensation, equipment, patient care, alterations and renovations, stipends and tuition, consortium/contractual costs, and F&A costs.
2. Determine requirements for and approval of institutional/departmental cost-sharing.
3. Review clinical trial protocols and confer with clinicians to develop clinical trial budgets.

Clinical Trial Agreements, Contract Negotiation, and Processing (1.5 hours)

An overview of the clinical trial agreement and contract process, from initial review, through negotiation and finalization, will be provided. Featured in the presentation will be standard and LSU-required clauses, as well as troublesome or complex language to avoid.

Primary Target Audience: Investigators (all levels), Business Managers, Assistant Business Managers, Administrative Coordinators, and Research/Study Coordinators and Nurses

At the conclusion of this activity, the learner should be better able to:

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1. Follow the steps to opening a clinical trial.
2. Recognize potentially problematic clauses and language in clinical trial agreements and related contracts.
3. Negotiate favorable contract terms with outside entities.

Office of Technology Management Refresher and Policy & Procedures Update (1.5 hours)

This presentation by the Director of the LSUHSC-NO Office of Technology Management (OTM) will cover intellectual property issues, the role of the OTM in institutional operations relative to new technologies developed by investigators, a brief description of the patenting process, and several policy and procedures update. Specifically, the new MTA process will be discussed as well as planned policies for faculty startups.

Primary Target Audience: Investigators (all levels), Business Managers, Assistant Business Managers, Administrative Coordinators, and Research/Study Coordinators and Nurses

At the conclusion of this activity, the learner should be better able to:

1. Differentiate between various types -- and accurately identify ownership of -- intellectual property including patents, trademarks, and copyrights.
2. Understand the technology licensing process.
3. Become familiar with OTM's policies and procedures, in particular the MTA process and planned policies for faculty startups.

NIH Public Access Policy/Using My NCBI (1.5 hours)

This presentation will provide a brief overview of the NIH Public Access policy, and will provide instructions on submitting peer-reviewed manuscripts/articles arising from NIH-funded research using My NCBI's "My Bibliography" tool.

Primary Target Audience: Investigators (all levels), Business Managers, Assistant Business Managers, Coordinators, and anyone who has been delegated an investigator's authority to use Commons

At the conclusion of this activity, the learner should be better able to:

1. Ensure compliance with the NIH Public Access Policy.
2. Submit manuscripts funded by NIH monies to PubMed Central (PMC) using one of four methods described.
3. Utilize My NCBI to link publications with funding sources, save citations, manage bibliographies, and search for publications.

The NIH Peer Review Process (1.5 hours)

The NIH's "Enhanced Peer Review" system will be reviewed, with an explanation of the scoring system and how it relates to application preparation. Participants will be shown a sample summary statement, as well as a sample reviewer template.

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Primary Target Audience: Investigators (all levels), Business Managers, Assistant Business Managers, and Coordinators

At the conclusion of this activity, the learner should be better able to:

1. Manage peer review of submitted grant applications by directing them to a specific Scientific Review Group and by crafting applications to be responsive to review criteria.
2. Interpret NIH review scores and summary statements.
3. Appeal reviews if necessary, appropriate, and approved.

When In Doubt, Route (1.5 hours)

The focus of this presentation will be to instruct the audience about the "who-what-when-where-how-why" related to materials that need to be routed through the Office of Research Services (ORS) for institutional review, approval, and signature. Included is a tour of the ORS routing sheet.

Primary Target Audience: Investigators (all levels), Business Managers, Assistant Business Managers, and Coordinators

At the conclusion of this activity, the learner should be better able to:

1. Determine who needs to route grant and contract-related materials, what specific items should be routed, when they should be routed, where documents are processed, and why materials should be reviewed.
2. Chose the best method for routing grant and contract-related materials.
3. Prepare, accurately and completely, the Office of Research Services' routing sheet.

Institutional Review Board (IRB) Basics (1.5 hours)

The ethical framework for human subjects research and regulations related to human subjects research will be discussed. Completion of an IRB application will be covered. Also included will be a discussion of required CITI training and registration of studies in Clinicaltrials.gov.

Primary Target Audience: Investigators (all levels), Business Managers, Assistant Business Managers, and Coordinators

At the conclusion of this activity, the learner should be better able to:

1. Recognize the research conditions under which IRB approval is required.
2. Locate and complete the required training through CITI as a first step in securing IRB approval.
3. Submit a complete and accurate IRB application, while avoiding common errors and omissions.

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Institutional Animal Care and Use Committee (IACUC) and Institutional Bio-Safety Committee (IBC) Application Basics (1.5 hours)

The mechanics of IACUC and IBC application processes will be discussed. Instructions on completion of the IACUC and IBC applications will be given. Components of the applications will be discussed in relation to the use and care of research animals, the principles of animal welfare program and animal and biosafety regulations.

Primary Target Audience: Investigators (all levels), Business Managers, Assistant Business Managers, and Coordinators

At the conclusion of this activity, the learner should be better able to:

1. Recognize and re-state the basic tenets of federal animal welfare and bio-safety policies.
2. Navigate the LSUHSC-NO Office of Research services web site to locate and download IACUC and IBC application forms.
3. Submit complete and accurate IACUC and IBC applications, while avoiding common errors and omissions.

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ARCHIVED PRESENTATIONS:

[Preparing the NIH Research Performance Progress Report \(RPPR\) \(May, 2014\)](#)

[\(Click for video\)](#)

[Using the HRSA Electronic Handbook \(EHB\) System \(September, 2012\)](#)