

**Office of Research Services
Professional Development
Knowledge Base/Presentation Archive**

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PRESENTATION DESCRIPTIONS

Grants.gov

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

A tour of a “typical” NIH grant application is conducted, with instructions for completing each section provided. Emphasis is 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

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, GrantForward, 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:

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

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 provides participants with the background necessary to develop a competitive funding proposal. This session is conducted by an experienced, successful NIH-funded Principal Investigator.

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.

Conducting a Medicare Coverage Analysis for Clinical Trials

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

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 focuses 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

An overview of the clinical trial agreement and contract process, from initial review, through negotiation and finalization, is provided. Featured in the presentation is 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:

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.

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

The mechanics of IACUC and IBC application processes is discussed. Instructions on completion of the IACUC and IBC applications is given. Components of the applications are 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.

NIH Public Access Policy/Using My NCBI

This presentation provides a brief overview of the NIH Public Access Policy, and provides 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

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

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

The focus of this presentation is 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

The ethical framework for human subjects research and regulations related to human subjects research is discussed. Completion of an IRB application is covered. Also included is 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.

Office of Technology Management Refresher and Policy & Procedures Update

This presentation by the Director of the LSUHSC-NO Office of Technology Management (OTM) covers 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 updates, including the MTA process and 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 policies for faculty startups.

Preparing the NIH Research Performance Progress Report (RPPR)

Federal agencies have implemented a federal-wide Research Performance Progress Report (RPPR) for submission of required annual or other interim performance reporting on research grant and cooperative agreement awards to standardize recipient reporting on federally-funded

research projects. For the NIH, the RPPR will replace the now-familiar eSNAP reporting system in Commons. This presentation provides an overview of the new reporting format and offer tips for successful report completion and submission.

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

Using the HRSA Electronic Handbook (EHB) System

HRSA, the Health Resources Services Administration, is the primary Federal agency for improving access to health care services for people who are uninsured, isolated or medically vulnerable. HRSA uses a grant application system typically consisting of two phases: a Grants.gov submission, and a subsequent submission through HRSA's own "Electronic Handbook" EHB system. This session provides information on how those two systems work together.

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

Using eRA Commons

This presentation provides 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, progress reports, final reports/closeouts, invention statements, and relinquishing statements. Performing Internet-assisted reviews, managing training grants via xTrain, changing institutions, and preparing an application for an administrative supplement are also covered.

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