Title Page: NIH Grant Writing

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Slide 2: No Title

[image}
Scientist (cartoon figures) setting up a 'drip' sample and one scientist at a keyboard typing. The scientist is typing "Dear sir, Could we please have a grant of $500,000 from your corporation to allow to research possible antidotes to novel new colorless, skin absorbed and slow-acting nerve toxin? P.S. It is possible that some of this toxin may been inadvertently spilled on the envelope.
[end image]

Slide 3: No Title

[image}
N I H Grant Proposal flow process.

- Proposal goes to Scientific Review Panel: Scientists evaluate scientific merit of grant proposal
- Then to Program Officer: Main contact for applicant Helps interpret review results
- Then to Institute National Advisory Councils: Assess programs Approve applications Public members
- Then to Institute Director: Makes final decision Allocates funds Provides annual justification
- to Congress
- Funds come from Congress and sent to the researcher:
    - Initiates grant proposal:
        - New project
        - Continuing project

[end image]

Slide 4: Understanding the Grant Process

The Best Approach?
[image]
cartoon figure getting ready to go through the first doors of many doors behind that door.

[end image]

Slide 5: Successful grant writing is a mixture of:

- Good Science
- Good Communication
- Good Marketing

[image]
Executive type talking to a scientist in the R&D department. The executive says "Just your regular experiments, Dr. Brainstorm. Leave the new improved and miracle breakthrough stuff to our advertising department."
[end image]

Slide 6: Pre-Submission Planning Timeline

[image}
Month before receipt date:

- Planning phase:
  - Beginning: Assess yourself, your field, and your resources
  - 8 months: Brainstorm; research your idea; call N I H program staff
  - 7 months: Set up your own review committee; determine human and animal subject requirements
- Writing Phase:
  - 6 to 3 months: First outline your application's structure; then write your application
  - 2 months: Get feedback; edit and proofread
- Submission Phase:
  - 1 month: Meet institutional deadlines
  - 0 month: Receipt date

[end image]

Slide 7: No Title

[image]
cartoon Vikings coming back to their ship after ransacking a town. The ship is on dry land because the tide has gone out. The leader says "Everyone can just put down their loot and plunder; and Sven here - - yes, old Sven, who was in charge of reading the tide chart - - has something to say to us all."
[end image]

Slide 8: Identify an NIH home for your idea

- Share your 2-3 page concept paper with an NIH program official and request feedback
- Is your Institute interested in funding research like this?
- Are there others who are currently funded to do similar work?
- Does this fall within a priority area of research for your Institute
- How can I improve this concept?

NOTE: You can request assignment to one or more NIH Institutes!

Slide 9: Why Contact a Program Official?

- To make sure your topic is of interest to the branch/division/Institute
- Submitting a concept paper for feedback helps define interest, but
    - PO's cannot design your study or suggest projects you should propose – you need to decide what you want to study
- To get advice about the application & review process
- To get advice on what grant mechanism is appropriate for this type of research proposal?
- To get advice on what funding opportunity announcements does your institute participate in that would be suitable for this concept?

Slide 10: Charting a course for proposal preparation: considerations

- Do you need to collect preliminary data?
- Will your proposed idea require more than $500K in support (direct costs) from NIH in any given year?
- How much time will it take to secure the cooperation and support of key stakeholders and letters of commitment?
- How much time will you need for your key team members and consultants to review and comment on the content?

Slide 11: Applying as a New Investigator or Early Stage Investigator

- New Investigator: has not previously competed successfully as PD/PI for a significant NIH independent research award
- Early Stage Investigator: New Investigators within ten years of completing their terminal research degree or medical residency
- Traditional NIH research grant (R01) applications from ESIs will be identified and the career stage of the applicant will be considered at the time of review and award

Slide 12: Submitting a Multi-PI Application

- The multi-PI option is for investigators seeking support for projects or activities that require a team science approach
- A contact PI is responsible for communication between the NIH and the leadership team
- Awards involving PIs at different institutions are managed using subcontracts
- NIH policies related to New Investigators will be applied to multi-PI applications only when all PIs involved are classified as New Investigators

Slide 13: New review criteria

- Significance
- Innovation
- Approach
- Investigator(s)
- Environment

*Do not have to be strong in all areas

Slide 14: Scoring criteria

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
High	2	Outstanding	Extremely strong with negligible weaknesses
High	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Very strong with only numerous minor weaknesses
Medium	5	Good	Strong but with at least one moderate weakness
Medium	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
Low	8	Marginal	A few strengths but with at least one major weakness
Low	9	Poor	A few strengths and numerous major weaknesses

Slide 15 Significance

- Why is this study significant?
    - Tell the reviewers what is significant – don't assume that they will see it as you do
        - This study is significant in the following ways:
        - Diversion of pain medications is a pressing problem requiring systemic intervention
            - Summarize relevant literature, statistics, etc. to back this up

        - Co-location of pharmacy services may improve patient retention and compliance
            - Summarize relevant literature on retention/compliance and
            - research on other co-location studies

Slide 16: Innovation

- Why is this study innovative?
    - Tell the reviewers what is innovative – don't assume that they will see it as you do
        - This study is innovative in the following ways:
        - There are no studies about whether outcomes are improved with on-site access to pharmacy services
            - Be sure you do a thorough literature review before making this kind of claim!
        - This study represents a rare partnership between a state pharmacy board and drug treatment providers
            - Back up with literature on how this differs from usual practice

Slide 17: Alignment of application with new review criteria

Core Review Criteria	Application Sections
Significance	Research Strategy
Innovation	Research Strategy
Approach	Research Strategy
Environment	Resources
Investigator(s)	Biosketch (Personal Statement)

Slide 18: No Title

[image]
N I H Grant application

- Abstract: 1 page, All Mechanisms
- Specific Aims: 1 page, All Mechanisms
- Research Strategy:
    - 6 Pages, R03, R21
    - 12 pages, R01
- Biographical Sketch
- Resource & Facilities: 4 pages

leads to fundable N I H Grant Application
[end image]

Slide 19: Anatomy of a Grant Application: Administrative Sections

Face Page
Abstract
Table of Contents
Budget for Initial Budget Period
Budget for Entire Project Period
Biographical Sketch
Other Support
Resources
Checklist

Slide 20: No Title

- Title (the "Hook")
- Clear and descriptive

[image]
fishing lure with two treble hooks
[end image]

Slide 21: Cover Letters

- May suggest funding institutes
  - Often refer to contacts with program officials
  - May request multiple assignment
- May suggest study section assignments
- May identify conflicts of interest
- May identify key expertise needed for review
- SRO may contact applicant if requested assignment is not optimal
  - Expertise
  - Focus of committee
  - Conflicts of interest

Slide 22: Project Summary/Abstract

- This is first part of the application that is read
- Best (and easiest) to write this last.
- Provide brief description of all major aspects of proposed project.
- Summarize purpose, importance, background and feasibility of research; relevant data; target population; hypothesis and methodology; data analysis and expected results.
- If funded, this abstract will be public record and searchable in public NIH databases.

- Slide 23: Abstract - Summary of the proposal

Abstract Section	# of Sentences
Background	2 - 4
Rationale	1 -2
Aims/Objective	1
Methods	5 - 7
Implications for anticipated results and contributions to public health	1 - 2

Slide 24: Specific Aims

- The Specific Aims page is the first full page reviewers will read
- Needs to stand on its own as a snapshot of the proposal
- Needs to capture the reviewers' attention
    - Does this project sound interesting and innovative?
    - Does it sound feasible?
    - Does it pass the "so what" test?
- This page also may determine review committee assignment
    - Be clear about your goals

Slide 25: Specific Aims

- What you want to learn by conducting this study
- Begin with brief description of overall short- and long-term goals and importance of the study
- State the aims in measurable terms:
    - Do not just describe process!
    - *Example:*
        - Aim 1: Determine whether co-location of pharmacy services impacts number of prescriptions filled/re-filled.
        - Aim 2: Compare patients assigned to on-site versus off-site pharmacy on medication compliance & diversion.

Slide 26: Hypothesis

- Most NIH research is <u>hypothesis-driven and theoretically based</u>.
    - This differs from program evaluations.
- Hypotheses are more specific predictions about the nature and direction of the relationship between two variables.

- You design your study to test these hypotheses.
- *Example:*
  - Greater cultural identity will serve as a protective factor and relate to decreased drug abuse.

Slide 27: Background and Significance Prototype

- What is known about the condition or disease in the population being studied?
  - Site and discuss current articles that support your study aims and articles that demonstrate a gap in the research
- What is known about the independent variables being studied?
- How well is the endpoint usually measured?
- How does the study address an important public health problem
  - How will your study fill the gap in the research

Slide 28: Preliminary Studies/Progress Report

- Provide information that will help to establish the experience and competence of the investigator to pursue the proposed project
- Competing continuation grants should summarize the previous application's specific aims and the progress made toward them
- May list publications relevant to or supported by prior grant and submit up to 10 manuscripts in Appendix
- Usually 6-8 pages

Slide 29: Preliminary Studies Prototype

- What is your experience with the proposed study population or animal model?
- Can you precisely and accurately measure the endpoint variables?
- Can you precisely and accurately measure the dependent (outcome) variables?
- Can you manage and analyze the data?

Slide 30: Reasons To Do a Pilot Study

- Demonstrate ability to recruit/access/retain study population
- Establish ability to perform assay reproducibility, validity, precision, accuracy, etc
- Estimate prevalence/incidence of endpoints
- Quantify variability and magnitude of change in endpoint for purpose of sample size calculation

Slide 31: Approach

- Describe exactly how you will carry out the proposed study
- What hypotheses will you test?
    - How do these relate back to the Specific Aims?
- What study design will you use?
- Who are the subjects of the study?
- What data will you collect from them?
- How will you analyze those data? How will you decide if your hypotheses were confirmed?

Slide 32: No Title

Research: Methods

Slide 33: Research Design and Methods

- Overall Study Design
- Patient Population
- Data Collection
- Endpoint Definition
- Data Management
- Data analysis
    - Sample Size Calculation
- Study Strengths and Limitations
- Timeline

Slide 34: Study Design

- Descriptive, comparative, longitudinal, case-control, quasi-experimental, randomized
- Example (randomized design):
    - Half of the participants will be randomly selected to participate in a paraprofessional home visiting intervention with the remainder receiving optimized care as usual.
- State why this design was chosen
- Use a diagram, if needed, to clarify

Slide 35: Sampling Plan

- Include sampling frame, study setting and sample size

- Criteria for inclusion or exclusion
- Method of selection and group assignment
- Results of power analysis
- Estimated attrition and how it will be handled
- Consult with and include a Biostatistician

Slide 36: Data Collection Procedures

- How will data be collected?
- Who will collect data?
- What procedures will be used?
- What will be the basic protocol for data collection?
- How many data collection points and why?
- How will subjects be tracked for a follow-up?

Slide 37: Data Collection Instruments

- Brief description of instruments (with established reliability and validity data)
    - Process by which community review boards will determine instruments
    - Process for adaptation and ensuring validity
- If possible, include a copy of each instrument (or prototype) in Appendix
- Discuss procedures for training researchers or interviewers and for data collection

Slide 38: research Strategy: Data Analysis

- **Quantitative designs**
    - Consistent analytic plan and approach for each aim (basic to complicated)
    - Use highest order analysis (descriptive to multivariate)
    - Link analyses to Aims, Hypotheses
    - Include biostatistician from beginning
- **Qualitative designs**
    - Detailed analysis and specifics, software

TIP: *NIH Qualitative Methods in Health Research Opportunities and Considerations in Applications and Review*: *http://www.obssr.od.nih.gov*

Slide 39: Data Analysis

- What statistical procedures and methods will you use to analyze data for each hypothesis being tested?

- A strong data analysis plan should go beyond simple statistics and include multivariate analyses and analyses that control for the effects of extraneous variables or conditions.
- Address the issue of missing data.

Slide 40: Qualitative Research: Keys to Success

- Systematic description of data collection methods
- Clear and convincing rationale why qualitative method is most likely to produce useful findings
- Clearly described sampling plan
    - Describes relationship to population of study

Slide 41: Qualitative Keys to Success: Continued

- Specification of timeframes that bound data collection
- Careful presentation of the data to be collected
- An orderly account of the analytic procedures
    - Include how finding can be interpreted

Slide 42: Important to Remember!

- Goal of Analysis Section:
    - Demonstrate use of sound scientific techniques
    - Minimize the number of assumptions reviewers make about the study
- Make sure the analysis plan corresponds with the study aims & hypotheses
- Justify all of your decisions
    - Explain why you proposed what you did and why not something else

Slide 43: Study Limitations

- Give a brief discussion on limitations of the proposed study and alternative methodologies, if necessary.
- Maintain delicate balance – don't give too many limitations, but at the same time, don't ignore obvious ones.
- Reviewers want to see that you have thought through the alternatives.

Slide 44: Research Strategy: timeline

- Dissemination Study Procedures
    - Material Development: Year 1

    - Focus Group: last half of Year 1
    - Pre-Implementation Chart Audit: last half of Year 1
    - Implementation: last part of Year 1 to middle of Year 3
    - Post-Intervention Chart Audit: latter part of Year 3
    - Evaluation: latter part of Year 3 to first 3/4 of Year 4
    - Data Analysis: middle of Year 3 to middle of Year 4
- Process Data Procedures: middle and latter part of Year 2 and latter part of Year 3
    - Key Informant Interviews and Focus Groups: latter part of Year 1 to middle of Year 4
    - Data Analysis: latter part of Year 1 to middle of Year 4
- Report Writing: latter part of Year 1 to middle of Year 4

Slide 45: Human Subjects

This is a separate section (doesn't count against 12-page limit).

- Discuss handling of human subjects and confidentiality issues.
- Discuss possible risks to study participants, with procedures to prevent dangerous situations.
    - Risks include both physical health risks as well as compromising subjects' privacy.
- Go to OHRP's web page (http://grants1.nih.gov/grants/policy/hs/index.htm), ie IRB, Target Enrollment, Human Subjects Education Certificates

Slide 46: Human subjects, recruitment, informed consent

- **Human subjects**
    - Inclusion of minorities, women, children, genders
    - Protection
    - Exemptions, if applicable
    - Potential benefits / risks

- **Recruitment and informed consent**
    - Vulnerable populations
    - Incentives
    - Informed consent
        - Participation
        - Use of information
        - Future analyses

Slide 47: Targeted/Planned Enrollment Table

[image]
Targeted/Planned Enrollment Table form

[end image]
Reports the number of Individuals (by gender, ethnicity and race) you plan to enroll for the entire study;
Numbers should Not change

Slide 48: DSMP and data sharing

- **Data Safety and Monitoring Plan**
  - http://grants.nih.gov/grants/guide/notice-files/ not98-084.html
- **Policy on Data Sharing**
  - http://grants2.nih.gov/grants/guide/notice-files /not-od-03-032.html

Slide 49: Appendix

- For supplemental information/materials
- All pertinent information should be **in** the text. Reviewers are not required to read anything in the Appendix.
- Examples:
  - Surveys, data collection instruments

Slide 50: Other Pieces

- If you have partner organizations or consultants, you should include Letters of Support from them
  - State their commitment to the project and demonstrate that they know what they are committing to
  - These go in a section labeled "Letters of Support," not in the Appendix.

Slide 51: Resources and Facilities

- Instructions added to Resources
  - Provide a description of how the scientific environment will contribute to the probability of success of the project
  - Describe the institutional investment in the success of the investigator

Slide 52: Biosketches

- Anyone named as "Key Personnel" on an application needs a Biosketch
  - Key Personnel are people who are critical to the project
    - they cannot be replaced without NIH permission

- Biosketch contains:
  - Personal statement
  - Educational & job background
  - Publications (up to 15)

Slide 53: Biographical Sketch

Personal statement

- Briefly describe why your experience and qualifications make you particularly well suited for your role in the project

Publications

- Limit the list of publications or manuscripts to no more than 15
- Make selections based on recency, importance to the field, and/or relevance to the application

[image]
bidirectional arrow with text saying 4 pages inside the arrow
[end image]

Slide 54: Public Health Relevance Statement ("Project Narrative")

- This is a very brief (3-4 sentence) section in which you describe the public health relevance of this project.
- This section can be very helpful to NIH staff when making funding decisions.

Slide 55: Budget

Justify effort and expertise for all personnel

- New PI should be > 20% effort
- Consultants from other institutions are less expensive than "co-investigators"
- NIH Policy on Multiple Principle Investigators

Tip: http://www.grants1.nih.gov/grants/multi_pi index.html

Slide 56: Budget

[image]
Two guys talking in a lab with very little equipment, nothing on the shelves and one person sleeping behind a lab bench. One guy says to the other "The start-up fund didn't stretch quite as far as we thought they would."
[end image]

- Anticipate future salary / operating increases
- Include 1-2 trips for conference presentations
- Equipment and supplies
- Institutes often cuts budgets

Tip: Use of existing and shared resources is valued

Slide 57: Resources and Facilities

- Describe your institution/organization
    - May need to make a strong case for institutions with typically less research resources and facilities (e.g., nonprofits, local govt.)
- Be precise about resources you have for completing the project (e.g., computers, printers, Internet access, lab equipment, etc.)
- Reviewers will look at this section to evaluate the Research Environment. Make a strong case that the project has a high likelihood of succeeding in this organization.

Slide 58: Typical Timeline for a New Individual Research Project Grant Application (R01)

There are three overlapping cycles per year:

- Submit in February (June, October)
- Review in June (October, February)
- Council in September (January, May)
- Earliest award in December (April, July)

Cycle 1----
Cycle 2----
Cycle 3----

Slide 59: Important Mechanical Issues

- All applications are submitted electronically through Grants.gov
- All applicant institutions must be registered with Grants.gov and with eRA Commons.
- For many CBOs, this process will be made much easier by partnering with an academic institution
    - University would be the applicant org
    - CBO would be a sub-award

Slide 60: University Sign-Off for Applications

- University submits the proposal, not the investigator

- Information to classify and track proposal
- Administrative and Policy Considerations
    - Space requirements
    - Use of human subjects, animals, stem cells, etc.
    - Commercial potential
    - Conflict of interest
    - Debarment and supervision
- Sign-offs
    - Principal investigator, Chairperson, Dean
    - Sources of needed resources (space, GCRC, Biostatistics
    - Faculty from other departments

Slide 61: Support for Grant Submission

- **Contact Grants.gov Contact Center for questions on form functionality or submission of the forms to Grants.gov**
- **Contact the eRA Help Desk at NIH for technical issues that threaten NIH's timely receipt of your application**
    - **Work with the Grants.gov Contact Center and be sure to document the issue and provide NIH with the tracking number received from Grants.gov Contact Center**

Slide 62: Other Key NIH web-links

- Electronic Submission Intranet http://odoerdb2.od.nih.gov/ElectronicSubmission/index.htm
- Electronic Submission of Grant Applications http://era.nih.gov/ElectronicReceipt/
- Electronic Submission FAQs http://era.nih.gov/ElectronicReceipt/faq.htm
- Funding Opportunities and Notices http://grants.nih.gov/grants/guide/index.html
- Parent Announcements (For Unsolicited or Investigator-Initiated Applications) http://grants.nih.gov/grants/guide/parent_announcements.htm
- Standard Due Dates for Competing Applications http://grants.nih.gov/grants/funding/submissionschedule.htm

Slide 63: Helpful websites

- Office of Extramural Research (OER) Web Page http://grants.nih.gov/grants/oer.htm
- NIH Searchable Database of RFAs, PAs, and Guide Notices http://grants.nih.gov/grants/guide/index.html
- NIH Grants Policy Statement (Rev. 12/03) http://grants.nih.gov/grants/policy/nihgps_2003/index.htm

- NIH Extramural Nexus – Monthly newsletter (previously bimonthly) for the extramural community. http://grants.nih.gov/grants/nexus.htm
- RePORTER - Search to analyze an Institute's portfolio of funded projects, research areas, and more http://projectreporter.nih.gov/reporter.cfm
- Grant Application Basics http://grants.nih.gov/grants/grant_basics.htm

Slide 64: Before Submitting

- Choose an appropriate Review Group (locate listing of Review Groups and rosters via NIH Webpage)
- Use key words in title & abstract that will ensure an appropriate assignment for your application
- Be sure to observe any Institute-specific requirements when preparing your application

Slide 65: Common Pitfalls to Avoid

- Not significant, or exciting, or new research
- Too ambitious; too much work proposed
- Unfocused aims, unclear goals
- Project looks more like a program evaluation than a scientific research study
- Little or no staff expertise
    - Partner with qualified researchers who have experience getting and managing NIH grants

Slide 66: Common Problems in Applications

- Diffuse, superficial, or unfocused research plan
- Studies lack cohesiveness
- Lack of sufficient experimental detail
- Lack of knowledge of published relevant work
- Unrealistically large amount of work
- Uncertainty concerning future directions
- Lack of specific data

Slide 67: Common Problems in Applications

- Lack of new or original ideas
- Absence of an acceptable scientific rationale
- Lack of experience in the essential methodology
- Outdated methodologies
- Questionable reasoning in experimental approach

- Uncritical approach
- Poor preparation and presentation

Slide 68: Common Problems in Applications

- What is previous experience?
- Tribal Supports
    - Are support letters included?
- Is CBPR process evident?
- How will cultural expertise be assessed?
- How will you address confidentiality in a small community
- How will qualitative data be analyzed?
- Qualitative is not experimental method
    - Qualitative vs. grounded theory
    - Have someone read your grant application

Slide 69: Have someone read your grant application

[image]
Woman speaking to Dilbert and co-workers.
Woman says "And that's our new marketing video. We hope it will go viral."
Co-worker says "You'll have our comments by tomorrow."
Woman says "I'm not asking for comments. The video is already finished."
Dilbert says "The technology claims in the video are criminally inaccurate."
Woman says "I sent the script to engineering for comments 3 months ago."
Woman says "I got an email back from someone named Wally who said it was great."
Everyone looks at Wally, sitting behind Dilbert, drinking a drink out of a coffee mug."
Wally says "I thought she was asking if it was funny."
[end image]

Slide 70: Obvious and not so obvious: For Success Proposal

- Organized, lucid write-up
    - Crisp, clear story of presentation
- Link aims, hypotheses, measures, analyses
    - Don’t assume reviewers “*will know what you mean”*
- Include well-designed tables and figures
    - Link measures to theory and literature
- Hook-up
    - With successful NIH mentor with funding

Slide 71: General Writing Tips for NIH Applications

- Keep readers in mind (avoid acronyms)
- Reviewers will have general knowledge but may be unfamiliar with your specific area or population – don’t make assumptions.
- Format (use headings: bold,

Read and follow the directions!
[image]
A group of people sitting around a table. One person says "Agreed. We fund only those proposals we can understand."
[end image]

Slide 72: No Title

[image]
Snoopy typing a letter. "Gentlemen, Regarding the recent rejection slip you sent me, I think there might have been a misunderstanding. What I really wanted was for you to approve my application and me $250,000. Didn't you realize that?!!"
[end image]

Slide 73: Questions?

[end presentation]