A Little Introduction to Proposal Development

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What we won’t discuss

• Fine-grained details of specific proposal development, e.g. NIH formats and requirements

  — But you can refer to these resources:
    • [http://grants.nih.gov/grants/grant_basics.htm](http://grants.nih.gov/grants/grant_basics.htm)
    • [http://research.unc.edu/index.htm](http://research.unc.edu/index.htm)

• The intricacies of study sections, summary statements, priority scores, and “paylines”
What we will discuss

• (Very, very) general introduction to funding —
  — Remember: it won’t be “your money!”

• Some strategies that colleagues and I have found to be successful;

• The importance of the proposal’s first pages;

• Good writing, good re-writing, good editing, good writing it again…

• Because, above all, you want to make things easy for your reviewers.
Funding sources:

• Federal Funding: open to all eligible applicants, but it is always worth while to investigate who else from UNC is doing what…and more RFA- than investigator-initiated these days! Some but not all federal funders:
  – **NIH**: counts most in academic medicine, and, thus, for academic career development, even though it has had a bench-oriented focus. [ NIH](http://grants.nih.gov/grants/oer.htm)
  – **AHRQ**: health services, outcomes, safety, comparative effectiveness: [ahrq.gov](http://ahrq.gov)
  – **CDC**: good for public health and population sciences approaches; [cdc.gov](http://cdc.gov)
  – **HRSA**: funds a number of training programs; [hrsa.gov](http://hrsa.gov)
  – **NSF**: National Science Foundation increasingly funds transdisciplinary work on health

• Foundation Funding: often, foundations do NOT want to hear directly from you, or they will receive only letters of intent: investigate before you approach!
  – Large funders include Robert Wood Johnson [rwjf.org](http://rwjf.org), the Commonwealth Fund [cmwf.org](http://cmwf.org), and Kaiser Family Foundation [kff.org](http://kff.org) although lately Kaiser has made fewer external awards and does more internally driven projects.

• Other, unusual opportunities arise…we just keep a close lookout for these!
Kinds of federal awards, roughly speaking:

• **GRANTS:**
  
  – Investigator-initiated federal award (for NIH, the “R01” award): the gold prize, the full, large-scale, multi-year proposal. A falling proportion of federal awards fall into this traditional category.
  
  – Awards chosen for funding in response to RFAs (Requests for Applications): the much more common route to large, multi-year awards.
  
  – Center and Program Awards and Cooperative Agreements: federal mechanisms for supporting institution-wide or multi-institution endeavors.
  
  – Various Pilot Awards and Small Grants: R03, R21 and the like – these are federal mechanisms for supporting new projects or young investigators in limited, preliminary studies.
  
  – “Training Grants” – all the (seemingly endless) series of “K Awards” to support the development of young careers. These require very significant matching from the department/institution – but UNC has a well-developed process for submitting K applications.

• **CONTRACTS:**
  
  – Another kettle of fish entirely, and we won’t discuss them here – nor will we discuss industry awards.

• **COOPERATIVE AGREEMENTS:**
  
  – Hybrids between grants and contracts; generally emerge as specific RFAs, and funding agency will have high involvement.
Kinds of non-federal awards, also roughly speaking:

• **GRANTS:**
  - Often work in ways that are quite similar to the ways of federal awards — you have project officers, budgets, and reporting requirements. The foundation may want to be a partner in the endeavor, and this can often make for a wonderful collaboration.

• **FELLOWSHIPS and SCHOLARSHIPS:**
  - These include Fulbrights, Robert Wood Johnson Clinical Scholar or Health Policy Scholar Awards, Ford Foundation Fellowships, and numerous other awards meant to support you while you engage in a novel, international, or career transition.

• Various small **INTERNAL GRANTS**: UNC, as is true of every major research university, has numerous small grant, pilot grant, and faculty research support programs. Some come from university or donor funds (e.g. University Research Council), and some can be thought of as “pass-through” awards – federal money awarded to a Center or program for the purpose of making pilot grants (e.g. the NC TraCS Institute, tracs.unc.edu)

*A tip: you are not “writing a grant,” no matter how often you hear it put that way. You’re “writing a proposal” that you hope will lead to a grant.*
What do all of these have in common?

• All are competitive! No easy $$, alas! Everything is even harder in current economic climate!
• All depend on your ability to convince reviewers that, among many good applications, yours stands out.
• All have missions, expectations, or want to advance a particular paradigm or perspective.
• All subject your application to a review process
Proposal review

• “Study Sections,” Panels, and Review Committees
  – These are composed of substantive experts who, generally, also
    have successful grant experience are empanelled by the funding
    entity to review proposals
  – They compare, rank, score, criticize proposals.
  – They may not have explicit, sub-specialist knowledge of your
    exact area, but will make judgements about it anyway.

• Scoring and “triage”
  – Whether the scoring is on the new NIH 1 (wonderful) to 9 (awful)
    scale, or whether the “letter of intent” followed by invitation to
    submit full application, many – most – proposals don’t get past
    the first stage –
    • So please don’t be downhearted if/when your first attempt is not
      funded – but it is all right to kick the wastebasket and rant about
      those who don’t understand your genius – for a day or two!
Given the odds, what is more likely than not to work?

• **Be responsive** to the RFA or to the funding entity’s mission and goals —
  — *Don’t fit round pegs in square holes, but do be open to adapting an idea to a funder’s aims.*

• **Be realistic** about what you can do within the broad guidelines and limits of the award.

• **Be rigorous:** follow all instructions, be very self-critical, and strive for a meticulous proposal, but...

• **Be ruthless** with yourself about the need to get it done —
  — *Don’t let the perfect be the enemy of the good!*

• **Be romantic:** let yourself fall in love with the work, with the idea! That’s what makes it worthwhile.
Specific Aims page

• **THE MOST IMPORTANT PART** of your proposal is the Specific Aims page.
  – If your Specific Aims (or equivalent) page is not articulate and persuasive, you lose the most important opportunity to capture the reviewers.

• *You may not be asked to produce a traditional Specific Aims page.
  – Follow the instructions VERY carefully to respond to funders’ requirement for the introduction of the proposal.
  – Use funders’ instructions and format to introduce your proposal as convincingly as possible.
  – Read it again and again with a very critical eye, and ask others to read it even more critically.
How do you build the Specific Aims page?

• Brief but very effective opening paragraph making problem – and your solution – crystal clear. Don’t waste space with flabby writing, with stating the obvious, or, conversely, with starting on such an obscure note that no one sees where you will go.

• Write (and re-write) elegantly concise and yet informative paragraph(s) showing your plans.
  – Show your responsiveness to the RFA, if applicable, right in the Specific Aims page.

• Specific Aims themselves:
  – try not to make more than 3;
  – don’t make lots of “sub-aims;” and
  – Make your Aims real proposals to do something (not hypotheses or conclusions).

• Specific Aims page is usually just one page, but not always!
Our PROPOS proposal

• I want to show you an effective and responsive opening to a proposal. In this case, the proposal is in response to a very specific RFA from the National Institutes of Child Health and Human Development: its goal is to fund “supplements” to the main CTSA award to develop better outcomes measures in response to the needs of the Better Pharmaceuticals for Children Act. Wayne Price was the project leader.

• One of the main targets in the RFA was to stimulate development of patient-reported outcomes measures. Another main goal of the research was to advance neonatal therapeutics.

• We took the rather challenging route of proposing to develop a proxy-reported neonatal outcomes instrument for Chronic Lung Disease – this was novel – really innovative (some may not use positive terms to describe its difference!).

• In the following example, I’ll try to show the “five r’s” – responsiveness, realism, rigor, ruthlessness, and romance – and some good writing too – all to what turned out to be successful effect!
INTRODUCTION

Problem to be addressed. Chronic Lung Disease (CLD) is a common and important problem in a vulnerable population, premature infants. CLD is a primary or secondary endpoint for the efficacy of many treatments used in premature infants. The severity of CLD is also an important predictor for long-term outcomes in premature infants. Current biometric assessment tools for CLD provide a gross measure of the severity of disease but do not capture the nuances of functional limitations related to lung pathology.

Hypothesis. Adaptation of Patient-Reported Outcomes Measurement Information System (PROMIS) methodology will allow creation of a detailed and reliable outcome measurement tool for defining the severity of CLD based on functional, patient-related measures. Such a tool will improve our ability to evaluate interventions in neonatal medicine and to predict more accurately long-term outcomes influenced by CLD.

Specific Aim - Develop a robust, reliable, and accurate bedside measurement tool for assessing the severity of CLD that will supplement current biometric assessment tools.

Relevance to the goals of the supplement. The goal of this project is to foster “research on outcome measures in clinical and translational child health in priority areas as determined by the BPCA program administered by NICHD.” The 2008 BPCA Scientific Prioritization Meeting concluded that most of the drugs used in the neonatal intensive care unit (NICU) have never been tested in neonates, off-label use is common, and efficacy is hard to evaluate. Among the Meeting’s priorities was a call for evidence of the efficacy and safety of commonly used drugs. Our project will support this critical goal by developing a tool to grade the severity of CLD. Such a tool will allow evaluation of the effectiveness of drugs commonly used to treat CLD in the NICU without robust evidence, especially diuretics and inhaled bronchodilators, as well as interventions for the prevention of CLD such as ventilator management strategies, fluid administration, oxygen saturation limits, ‘late’ surfactant administration and antioxidant therapy. Other goals of the supplement are to “1) facilitate the development of qualified outcome measures and 2) relate non-clinical to clinical outcome assessments in child health for improving the evaluation of interventions or 3) assess and interpret clinical outcomes” and “improve the likelihood of success of pediatric clinical trials, especially drug trials, by identifying more reliable predictors of outcomes.” Our proposal accomplishes all of these goals. We will develop an outcome measure for CLD in collaboration with 4 other centers that will improve the ability of researchers to evaluate interventions in neonates and will improve clinicians’ ability to assess and interpret functional outcomes for infants with CLD.

Relationship between parent grant and supplement. The proposed project promotes several goals of the parent CTSA grant (TraCS Institute). This project will (a) develop teamwork within the institution (nurses, physical and speech therapists, physicians from different specialties) and across institutions (TraCS Goal 1); (b) find solutions to important health problems (TraCS Goal 1); (c) use advanced, state-of-the-art data analysis (PROMIS methodologies; TraCS Goal 2); and (d) create a mechanism for rapid dissemination of results (TraCS Goal 3). A major goal of the Pediatric TraCS is to provide a supportive organizational environment that fosters translational research for children (Pediatric TraCS Specific Aim 1). The proposed project is directly benefiting from TraCS-sponsored collaborations (PROMIS), expertise (statistical support), and organizational structure.

Relationship to the mission of the CTSA consortia. This project is transformative in that it will greatly increase the efficiency, quality, and speed of research related to CLD in premature infants by providing a more precise, reliable, and robust tool to quantify the severity of CLD. Such a tool will enhance the ability of investigators to determine the efficacy of interventions and has the potential to decrease sample size requirements for studies through greater precision in the outcomes measure. We will work collaboratively with the CTSA’s at Duke, Iowa, Stanford, and the University of Alabama to achieve this goal. Upon completion, the outcome tool can then be implemented at any program assessing outcomes related to CLD.

Unique aspects of the proposal. This project will greatly benefit from the expertise of the UNC PROMIS investigators. Also, the project will result in a collaboration of 5 nationally recognized neonatal research units, allowing rapid data collection on a large number of infants and increasing the tool’s reliability and validity.

BACKGROUND AND SIGNIFICANCE

CLD is one of the most common sequelae following preterm birth. The most vulnerable infants are those born before the 28th week of gestation (ELGANs). Approximately 30,000 ELGANs are born in the United States each year, and approximately half of them will develop CLD. A diagnosis of CLD is important because, compared to their peers without lung disease, ELGANs with CLD have increased mortality. Those who survive with CLD experience a prolonged initial hospitalization and an increased risk of neurodevelopmental impairment such as mental retardation and cerebral palsy. These CLD-associated morbidities lead to increased family stress, economic hardship, and increased health care costs throughout childhood.

Current CLD assessment strategies. The current definitions of CLD used in practice are unidimensional, focusing on the need for supplemental oxygen. Although more precise estimates of pulmonary function are available, they are difficult to adapt to premature infants, require specialized expertise and equipment, and are not used clinically in this population. The most common definition of CLD renders it a dichotomous diagnosis; receipt of oxygen at 36 weeks post-menstrual age (PMA). The NIH consensus definition divides CLD into none, mild, moderate, and severe based on the duration of oxygen therapy and the amount of oxygen received at 36 weeks. We believe that the definition of CLD needs further refinement by including functional PRO measures.

Potential benefits of improving the definition of CLD. Much effort, including many randomized, controlled trials, has been directed at preventing and treating CLD. All of these trials have used one of the definitions of CLD noted above. The only medications with a favorable risk/benefit profile include vitamin A and caffeine. Because pulmonary edema is thought to play a role in the development of CLD, many clinicians use diuretics to treat CLD despite minimal evidence for long-term efficacy and substantive side effects (electrolyte imbalance and bone demineralization). Similarly, bronchodilators are used by many clinicians with limited data on efficacy. We expect that refinements in the definition of CLD will allow clinicians and researchers to more effectively test therapies by accurately identifying subtle effects on CLD or by identifying subgroups of infants that respond to these therapies. The ultimate goal is to discover therapies that reduce pulmonary morbidity and other serious co-morbidities. In addition, refinement in the definition of CLD will allow more accurate prediction of important outcomes such as hospital length of stay and re-hospitalization after discharge and further refine the relationship between CLD and neurodevelopmental outcome.

RESEARCH PLAN

Specific Aim - Develop a robust, reliable, and accurate bedside measurement tool for assessing the severity of CLD that will supplement current biometric assessment tools.

Aim 1: Adapt PROMIS methodology to develop a bedside proxy (nurse and nurse practitioner)-reported outcome tool for assessing the functional severity of CLD at 36 weeks post-menstrual age in premature infants (the Proxy-Reported Pulmonary Outcome Scale, PRPOS).

Aim 2: Compare the PRPOS assessment tool to current definitions of chronic lung disease.

METHODS

PROMIS methodology is an extremely robust system of instrument item selection and refinement for patient-reported outcomes. We will adapt some of its techniques to develop the PRPOS. We will generate an inclusive list of potential items and responses, reduce and clarify the list using focus groups and cognitive...
Good features of this proposal

• This supplement RFA posed the puzzle of doing something novel and “translational,” and explaining it all, in *just 5 pages* – that called for very careful writing.
  
  — In this case, as you see, we did not have a traditional specific aims page, because of the unique instructions,
  
  — but we were careful to include our specific aims on the first page nonetheless

• In our response, we are careful to highlight the RFA’s specific requirements (including partnering with other major federal research programs such as PROMIS). We wanted to make it easy for reviewers to see both our novel idea, and its responsiveness to the RFA’s objectives.

• We wrote in active voice, with careful attention to creating clear, readable text. We could not count on having reviewers who were neonatologists or survey instrument development experts. We had what we thought was a very clear discussion only after writing many drafts!

• Dr. Price was a wonderful, constructive, effective leader of a group effort – that is also irreplaceably important!
This proposal was funded – but…

• I believe most people would consider this to be a well-crafted, effective document even if it hadn’t been funded!

• That’s worth remembering: even very good proposals may not find funding.

• For all the myriad reasons something might not be funded, though, you never want poor writing, poor presentation, or poor explanation to be among them!
Before you did all this, though…

• You had to have a *research question*.

• Anyone who has spent time with a pre-schooler knows that the number of questions one can ask is virtually limitless.
  – Such questions frequently push the borders of knowledge (particularly questions that begin with ‘Why…?’),
  – but only rarely are they of the sort that falls into the category of scientific inquiry, at least in their first iteration.
  – “Why…?” may certainly generate a research question, but “Why…?” alone is usually not enough.
The characteristics of a good research question

• The question has inherent tension because it deals with a significant issue or controversy. The answer to the question will change the way people act or the way they think about the issue at hand.

• The question has generality. Answers will apply to situations beyond that within which it was immediately tested.

• The answer, by providing new insights, will make clear what new knowledge we need for fuller understanding

• The question can be answered with extant research methods. Methodology exists to answer the question and the experimental design needed to rule out alternative interpretations is feasible. If present methods cannot address the question (yet), it may be that the real research question is one of developing new methods that can.
Some examples of questions that aren’t research questions

• Are patients more satisfied with their treatment choices if they receive more information?
  – No one would be surprised if this question were answered in the affirmative. On the other hand, hypothesizing about the amount of information beyond which patient choice is befuddled rather than facilitated can be a very important research question, because it can be connected to, and advance, other areas of knowledge, and it can change practice.

• What is the optimal pH for immunocytochemical localization of the NMDA-N2B receptor subunit in thalamus of the C57BL/6 mouse?
  – This is a straightforward methodological question, with limited generality beyond a specific situation and very limited significance beyond the level of technique.

• Do physicians spend sufficient time counseling patients newly diagnosed with HIV?
  – This question is ambiguous (what is sufficient?) and what can be done once the answer is obtained? On the other hand, hypothesizing about the most effective counseling materials to assist physicians’ care of their newly diagnosed patients can be a valuable research question.
For Researchers

- Funding Sources
- Proposal Development Assistance
- Award Management
- Policies & Procedures
- Training Opportunities
- Publicizing Research
- Research Web Applications
- Forms
- FAQs
Welcome

The Funding Information Portal is a central repository of resources maintained by the Graduate Funding Information Center and the Office of Research Development that aids UNC-Chapel Hill faculty, staff, postdoctoral scholars, and graduate students in seeking information on funding sources for independent research, collaborative projects, fellowships, program development, and other scholarly activities.

Resources

Browse library resources by type using the options in the navigation menu to the left, or use one of the links below to find resources targeted to your group.

For faculty and staff...
...in the arts and humanities.
...in the social sciences.
...in the life and physical sciences.
...in the health and medical sciences.

For graduate students...
...in the arts and humanities.
...in the social sciences.
...in the life and physical sciences.
...in the health and medical sciences.

For postdoctoral scholars...
...in the arts and humanities.
...in the social sciences.
Accelerating Discoveries Toward Better Health

The North Carolina Translational and Clinical Sciences (NC TraCS) Institute at UNC-CH is one of 60 medical research institutions working together as a national consortium to improve the way biomedical research is conducted across the country. The consortium, funded by the NIH Clinical and Translational Science Awards (CTSA), shares a common vision to reduce the time it takes for laboratory discoveries to become treatments for patients, and to engage communities in clinical research efforts. It also is fulfilling the critical need to train a new generation of clinical researchers.

To achieve these goals, TraCS offers a number of programs and services to assist researchers through all phases of the process of translating basic science discoveries into meaningful health advances.

New TraCS Tools

Looking for a Clinical Trial?
Search our clinical trial database to find an opportunity that is right for you at researchstudies.unc.edu. Coordinators submit to the database and find other helpful resources at tracc.unc.edu/researchcentral.

Need Biobanking at UNC?
The NC TraCS Biobanking Consortium coordinates services to help investigators collect, process, and store human specimens for research. Visit the new

Access This Week’s External Funding Opportunities.
Visit the TraCS Grant Seeking Resources page to find external funding opportunities, additional funding resources and to chat with a librarian.

TraCS and NORC are working together to bring the best nutrition research services to researchers at UNC! Learn about the collaborative effort by visiting tracc.unc.edu/nutrition_research.
Thank you!

Questions?

image citations for first and last slides: