

Grantsmanship

Tips for Writing a Great Grant

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Topics

- How to write a good grant – the big picture and a few pearls
- Focus on NIH grants and NIH format
- Focus on the first page (Specific Aims)
- Will not talk much about budgets, biosketches, resources, or human/animal subjects

Credentials

- Written at least 3 dozen grants as PI and assisted in scores more.
- 25 federal & foundation grants
 - **14 as PI** (4 AHRQ, 3 VA, 2 NIH, 1 FDA, 1 FAER, 1 NPSF, & 2 APSF)
 - **7 as Co-PI and/or mentor** (3 NIH, 1 AHRQ, 1 NIST, & 2 APSF)
 - **5 federal grants as Co-investigator**

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Practice, Practice, Practice

- Grants are a unique writing form and style.
- It takes a lot of work to get good at it.
- Get help and mentorship from experienced grant writers.

Where do you start?

Ask questions about the world around you...



Grant Preparation Steps

- Have an important research question (the easy part)
- Find an entity who might want to fund it
- Design the experiment(s)
- Find appropriate collaborators
- Write the grant

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Don't do it if it you're not passionate about it!

- There's nothing worse than getting a grant & then having to do work that doesn't interest you.
- There are no shortage of good ideas ... don't pick a topic if you're not excited about it.
- Sometimes a little bit of research will get you excited but, if not, move on.

A Good Research Question...

- Is important (will have an impact)
- Is testable
- Can be feasibly addressed
- Someone will pay you to answer it

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Follow the money

- You are asking someone to give you money for something *you* want to do.
- Look at what the agencies want to fund.
- Targeted pots of money (e.g., RFAs) are much higher yield than unsolicited proposals.

Types of Grants

- **Federal**
 - **Response to RFA (U18, R18)**
 - **Investigator initiated (R01)**
 - **Career Development (K01, K08, K99R00)**
 - **Early stage/Pilot (R21)**
 - **Education/Training (R25, T32)**
 - **Smaller Grants (R03, conference grants)**
- **Foundation (AHA, FAER, APSF)**
- **Industry (typically contracts)**

Collaborators

- **Why?**
 - **If critical expertise is missing from the team.**
 - **Add stature or credibility to the proposal.**
- **What?**
 - **Will meaningfully contribute to the work being proposed (before and after funding).**
 - **Help significantly with the grant writing.**
- **If neither of the above, don't put them on the grant.**

The Grant Review Process

- Know the criteria by which the grant will be evaluated.
- Learn who will be the reviewers.
- Think about your competition.
- Write the proposal to stand out and to be exemplary.

NIH Scoring Criteria

- Overall Impact
- Significance
- Investigators
- Innovation
- Approach
- Environment
- Budget
- Responsiveness to RFA
- Generalizability
- Institutional Support/Commitment
- Human / Animal Subjects

1 (best) – 5 (worst) rating for each category and overall.

APSF Scoring Criteria

- **Significance and Relevance**
- **Innovation**
- **Responsiveness (to RFA)**
- **Technical Merit**
- **Applicability and Generalizability**
- **PI's and Team's Qualifications**
- **Environment**
- **Budget**

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Know the Reviewers

- Who are the likely reviewers?
- What are their interests, beliefs, and biases?
- What have they published? (NB: be sure to cite their relevant papers)
- Make sure you don't lose them on Page 1

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*It is not a technical report ...
or a novel*

- Tell a compelling story
- Get the key information across early
- Hammer home the key takeaways
- Grants should be written like an investigative journalism article in the *New York Times*

More Grant Writing Guidelines

- **Make sure the narrative flows**
- **Provide the key details**
- **Don't let the trees obscure the forest**
- **Make sure there are no inconsistencies**
- **Be clear and concise**
- **Follow the rules**

Traditional Grant Components

- Hypothesis and Specific Aims
- Background
- Significance
- Preliminary Results
- Materials & Methods
- Data Analysis
- Interpretation of Results
- Limitations
- Future Directions
- Project Management
- Timeline
- Human/Animal Subjects, etc.

The NIH Research Narrative

- **Specific Aims (1 pg)** – Brief precis of background & significance, Hypotheses, SAs, Precis of approach & expected impact
- **Research Strategy (11 pgs)**
 - Significance
 - Innovation
 - Approach

Specific Aims (1 page max)

- Why are you doing this study?
- What is innovative about what you will do?
- What is your hypothesis (or hypotheses)?
- What are the specific research objectives?
- How will you accomplish these objectives?
- What do you expect to find?
- What will your findings mean (i.e., impact)?

The grant has been divided into three Specific Aims on the basis of the opiate effects to be investigated: respiratory function (Aim 1), anti-nociception (Aim 2), and reinforcement (Aim 3). Aim 1 and 2 will employ well-established physiological models to study respiration (whole-body plethysmography and arterial blood gas analysis) and antinociception (paw withdrawal to a thermal stimulus). The opioid receptor pharmacology and *in vivo* dose-effect profiles of two systemically active delta-selective agonists, SNC80 and BUBU, will also be examined. Aim 3 will investigate the reinforcing effects of these novel delta agonists using intravenous self-administration as a well-validated animal model of drug abuse potential. Thus, the Specific Aims of this project are:

- Specific Aim 1: To elucidate the role of delta opioid receptors in *respiratory function*.
- Specific Aim 2: To elucidate the role of delta opioid receptors in *antinociception*.
- Specific Aim 3: To elucidate the role of delta opioid receptors in *reinforcement*.

Specific Aim 1: To test the relationship between specific factors associated with non-routine events (NRE) and the occurrence of anesthesia-related patient injury.

- **Hypothesis 1** – Based on our experience, and the literature, we postulate that the following five NRE-related variables will be positively associated with patient injury: a) type of NRE; b) the occurrence of multiple NRE; c) attending absence during NRE management; d) increased clinical workload post-NRE; and e) increased manual task demands post-NRE.

Specific Aim 2: To investigate in-depth the diversity of NRE-related variables and their potential risk of producing future patient injury.

- **Hypothesis 2** – Within a single class of NRE, those associated with airway management, there are preventable contributory factors identifiable using cognitive engineering methods.

The primary objective of the proposed work is to assess risk factors for medication errors in four academic hospitals using ecological momentary assessment (handheld survey tool) and direct structured observation (including behavioral task analysis). These techniques permit a multidimensional description of the interplay between clinicians and clinical work processes that will provide an understanding of factors contributing to medication errors and inform the design of interventions to prevent them. Medication errors will be captured through both conventional approaches (self-report and pharmacist intervention) and emerging methods (self-report using handheld computers and software checks of infusion pump programming).

Thus, the project's Specific Aims are to:

1. Demonstrate the feasibility of a novel handheld instrument (Dynamic Handheld Survey Tool) for real-time assessment of risk factors for medication error.
2. Identify the types of medication errors occurring among different disciplines (physicians and nurses) in multiple hospital settings and characterize the risks they pose to patient safety.
3. Identify factors in the inpatient adult and pediatric medical contexts that contribute to medication errors and that will be amenable to intervention through characterization of extrinsic and intrinsic factors.
4. Develop institutional-specific plans for targeted interventions likely to enhance medication safety.

The project's Specific Aims are to:

- 1. Develop standardized, generalizable simulation scenarios with associated valid, reliable performance assessment tools to conduct simulation-based assessment of BCA;**
- 2. Demonstrate that simulation-based clinical performance assessment can be reliably delivered across multiple national sites for the purpose of evaluating board-certified physicians seeking recertification;**
- 3. Describe quantitatively and qualitatively the distribution of clinical performance during simulation from a large and diverse cross-section of board-certified physicians;**
- 4. Begin to address the remaining challenges and questions related to reliable and valid simulation-based assessment of practicing physicians' clinical competency.**

The Specific Aims of this project are:

Mentored Phase

- 1. Carry out career development activities to transition the PI to an independent research role. Career development activities include didactic courses and seminars, an Independent Study project, and informal meetings, labs and conferences.**

Transition to Independence Phase

- 2. Describe, analyze and improve the system of people and technology that produces safe medication practice on an inpatient acute patient care unit. This project will use qualitative research methods to identify work practice routines that produce medication safety. A matrix will describe relationships between safe medication routines and attributes of technology that *support* or *create barriers* to safe practice. The PI will work with stakeholders to design and implement a work practice or informatics-based solution to improve medication safety.**
- 3. Describe, analyze and improve the system of people and technology that produces safe medication practice in an outpatient clinic. Ethnographic research in the Vanderbilt Eskind Diabetes Clinic will examine patient-provider interactions, use of informatics and other tools, and interaction with the dispensing pharmacy to gain a more complete understanding of potential barriers to medication safety.**
- 4. Evaluate the utility of specific qualitative methodologies in: 1) understanding work practice in context, 2) framing problems, 3) identifying solutions and 4) evaluating stakeholder experiences.**

Approach Material on the Specific Aims Page

Aim 1. (Months 1-9) will be accomplished by iteratively developing four standardized simulation scenarios (focused on clinical event management) based on the scenario requirements established by the ABA for the MOCA simulation course. We will concurrently refine published performance assessment tools to measure both medical/technical and behavioral performance, addressing known pitfalls. We will use a Delphi technique with a panel of 10-12 expert clinicians (not the investigators) to identify performance objectives critically important to perform (or to avoid) during the simulations, and to establish benchmark ratings for each performance objective. We will create videos of the 4 scenarios that exemplify the ranges of technical and behavioral performance. A subset of these video recordings will be used to train domain expert raters. Inter-rater reliability of the rating tools will then be assessed using different videos. *Our hypothesis (H1) is that domain experts can be trained to score video recordings of clinicians in high-fidelity simulation for medical/technical and behavioral performance with sufficient reliability to use in high-stakes assessment.* Aim 1's products will be 4 standardized scenarios, scenario-specific valid and reliable rating instruments, and new knowledge and methods for assessing clinical performance.

Grantsmanship Pearl

Sloppy Grants = Sloppy Science

- Word choice and grammatical precision
- No grammar or spelling errors
- No citation errors
- Consistency throughout

On Good Writing

- I am sorry I have had to write you such a long letter, but I did not have time to write you a short one (Blaise Pascal)
- Anybody can have ideas – the difficulty is to express them without squandering a quire of paper on an idea that ought to be reduced to one glittering paragraph (Mark Twain)
- Broadly speaking, the short words are the best, and the old words best of all (Winston Churchill)
- The difference between the almost right word and the right word is really a large matter – it's the difference between the lightning bug and the lightning (Mark Twain)

Now, Let's Look at Your Specific Aims



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Significance

- Importance of the problem in the context of what's known or currently done in the field (Background)
- How you are addressing critical barriers to progress or success in the field
- How the project will improve scientific knowledge, technical capability, and/or clinical outcomes
- How the project's results will change the field and improve human health

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How will it help grandma?

- Funders (e.g., NIH) must answer to their constituency.
- For the federal agencies, this is Congress and the Executive Branch who must ultimately get re-elected.
- Thus, your pitch must help them to sell the project to others.

Sample Significance Argument

- Patient safety is a big problem;
- Clinician performance deficiencies, especially for acute care events;
- Currently, there are not good measures of clinical competence;
- Simulation an attractive alternative for competency assessment;
- But not yet enough known / developed to do this validly & reliably;
- Anesthesia has made a good start at simulation-based testing;
- Proposed work fits in a continuum of development with the goal of valid and reliable simulation-based high-stakes assessment;
- Important to measure both technical and behavioral performance;
- Strong diverse team including national & international stakeholders;
- Methods and results will generalize to other specialties.

There is substantial public interest in assuring that practicing physicians are competent and able to consistently provide safe and effective patient care. Assurance of physicians' ability to detect and manage uncommon but potentially lethal events is an area of particular concern ¹⁻⁴ and may be amenable to simulation-based performance assessment ^{5,6}. However, the use of simulation for competency assessment, particularly for practicing acute care physicians, is still in its infancy ⁷. This multi-center collaboration proposes to address a number of necessary elements to conduct simulation-based clinical competency assessment, including: 1) the creation of standardized simulation test scenarios that can be consistently performed and reproduced; 2) the validation of associated reliable scoring methodologies; 3) the establishment of defining criteria for competency that are based on the performance during simulation of a representative cross-section of practicing physicians; and 4) the generalizability of these methods to other specialties. Moreover, when evaluating physicians (particularly as part of a high-stakes assessment), one must examine multiple dimensions of clinician performance including medical decision-making, technical skills, and interpersonal (also called behavioral or "non-technical") skills ⁸. Studies suggest that technical competence is insufficient to assure excellent care outcomes ^{8,9} – failures of communication and teamwork are frequent causes of adverse events ¹⁰⁻¹².

Reviewers' Comments on Significance

- “Simulation is gradually replacing traditional forms of learning ... Many types of skills can only be objectively measured through simulation ... simulation is becoming mandatory in specialties such as surgery and anesthesiology ... beneficial to identify performance outcomes and standardize the simulation scenarios”
- “Ensuring that practicing physicians maintain their skills and demonstrate competency in rare critical events will translate to improved care for patients and enhanced safety”
- “Assessment of competence for practicing physicians is an important and understudied problem ... could serve as a model for performing such assessments not only in this specific field (anesthesia), but in other healthcare settings. The involvement of multiple institutions will enhance the generalizability of results, as will the involvement of key stakeholders ... an important next step in the development of assessments of clinical competence”
- “...will build on the work of several prominent investigators in simulation education ... [anesthesiology] is definitely an inherently high risk area and is a significant area for patient safety improvement ... Vigorously tested methodology to allow the use of simulation in recertification and competency maintenance is scant and this project has very good potential for filling that knowledge gap”

Opiates are widely used for the treatment of moderate to severe pain despite a constellation of undesirable side-effects including addiction liability, respiratory depression, and sedation. These side-effects limit the range of uses and safety of opiate analgesia. While clinically important opiate effects have long been believed to involve a mu opioid action, more recent data suggest that agonists acting at non- μ (i.e., delta (δ) and kappa (κ)) receptors also produce analgesia. However, the side-effect profiles associated with activation of CNS δ or κ receptors have not been well delineated. The hypothesis of the proposed research is that the opiates' analgesic effects can be separated from their side-effects on the basis of opioid receptor-selective pharmacology. This is supported by the finding that analgesic doses of intracerebroventricularly (ICV) administered μ , δ , and κ receptor-selective agonists produce differential effects on opiate-induced analgesia, muscle rigidity, respiratory depression, and sedation (see Preliminary Results). The present application focuses on the δ opioid receptor system for three reasons ...

More Significance Examples

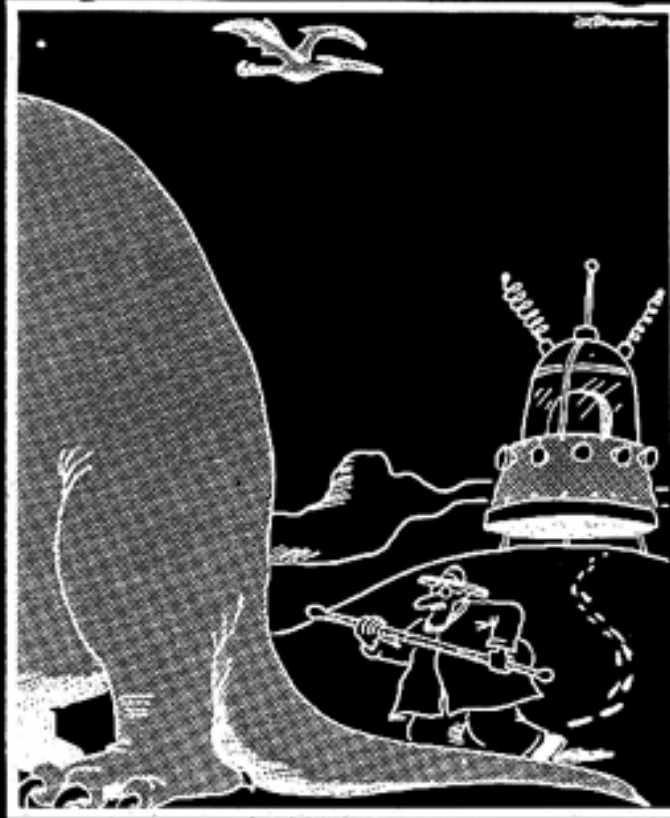
The proposed work will provide new insights into the relationship between workplace risk factors and medication errors. Understanding the contributing factors will assist in the identification of interventions to prevent or reduce the occurrence of medication errors. Importantly, this research will provide insight into the applicability and generalizability of risk assessment strategies across institutions and disciplines. Finally, the project will assess if a novel instrument, the DHST, is a cost-efficient and valuable risk assessment tool that can generalize to other settings and other risks to patient safety.

The focus of this proposed project is on anesthesia non-routine events during surgery. While our ultimate goal is to extend these methods to all surgical events, and to other medical domains, the narrow focus on anesthesia-centric events allows conduct of the work in a highly controlled and receptive environment where we can reliably collect granular data and draw conclusions about the causes of events that occur. About 350,000 anesthetics are delivered annually in the Veterans Health Administration (VHA). The VHA currently has no reliable data on the true incidence of anesthesia adverse events even though such events can be costly ⁵⁷⁻⁵⁹. Indeed, tort claims data from the TCIS database suggest substantial financial repercussions from deficient anesthesia care. Perioperative safety, a high priority in the VHA, could be significantly improved by understanding what aspects of anesthesia care predispose to patient harm.

Innovation

- What's new and exciting about your proposal?
- How are you challenging or trying to shift current scientific or clinical paradigms?
- What are the novel concepts, approaches, techniques, instrumentation or interventions to be developed or used?
- How have you refined, improved, or newly applied existing theories, approaches or methods, instruments, or interventions?

Innovation *and* feasibility ...



An instant later, both Professor Waxman and his time machine are obliterated, leaving the cold-blooded/warm-blooded dinosaur debate still unresolved.



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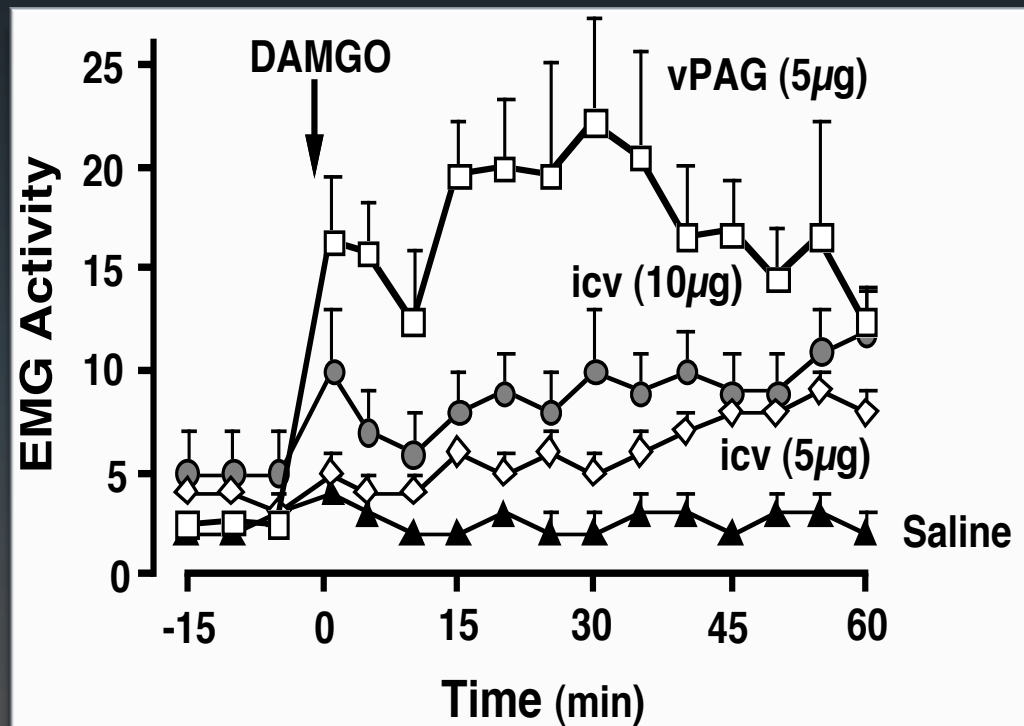
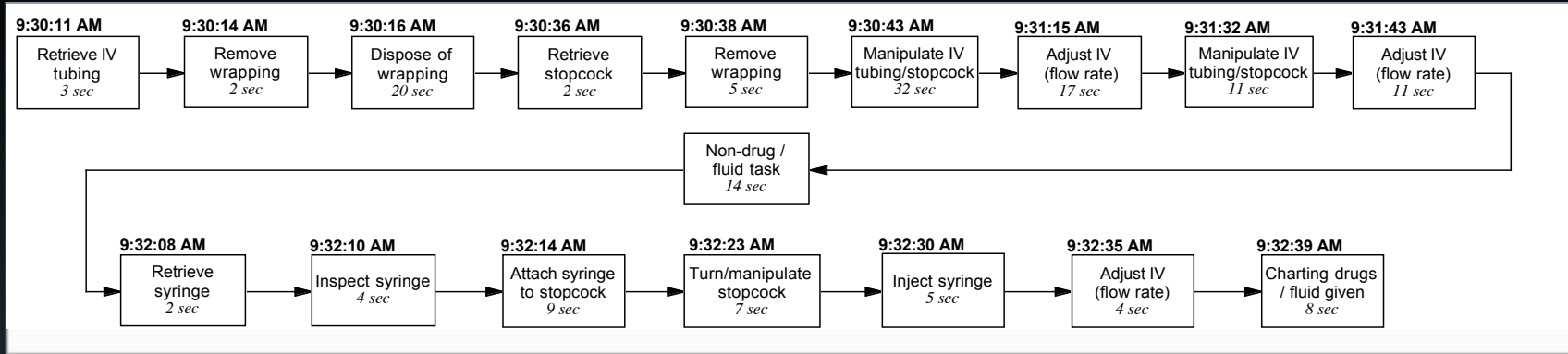


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Preliminary / Pilot Data

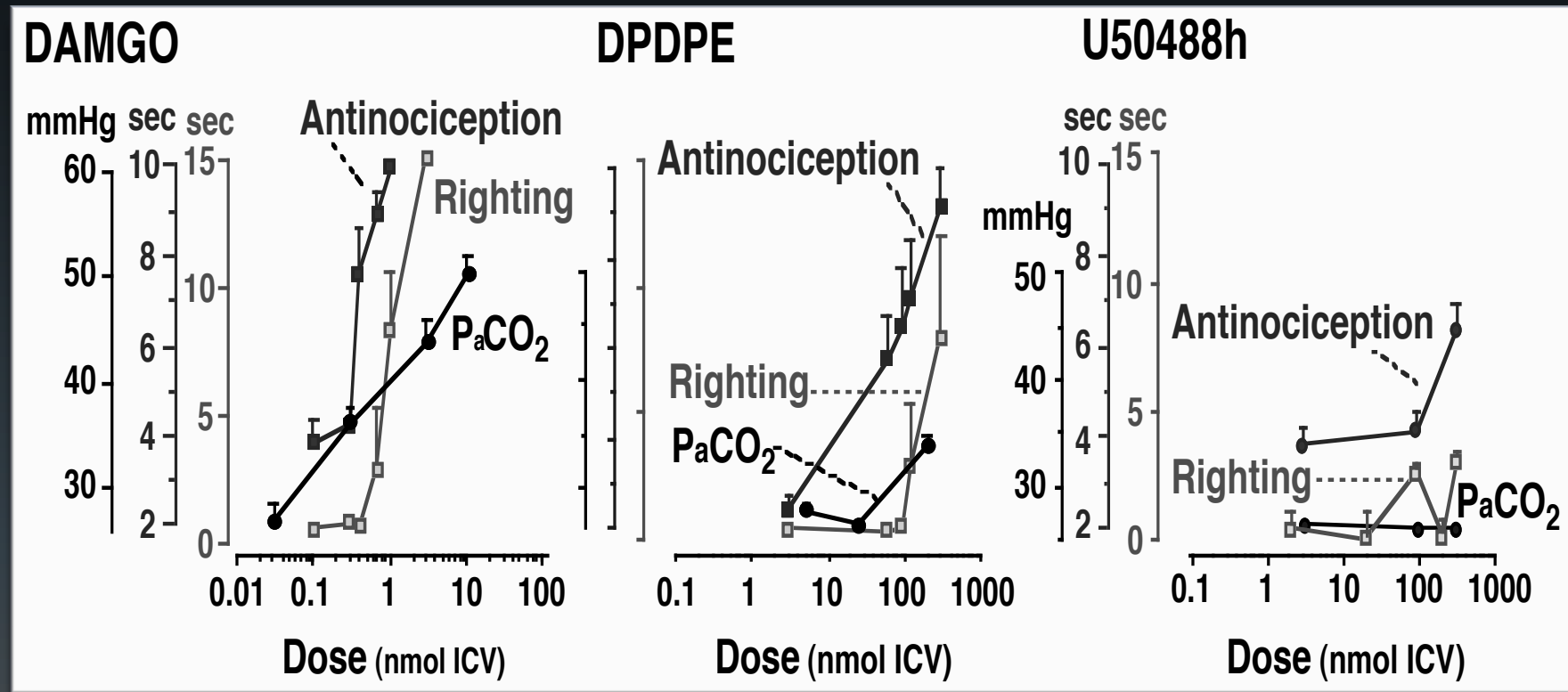
- **Critical to convincing reviewers of project viability and feasibility, especially for new investigators.**
- **Support your choice of design, methods, and power analysis.**
- **Shows → You are capable of doing the proposed work and that the research will yield the findings you claim.**
- **No separate section in new NIH format so must embed in Significance, Innovation, or Approach where appropriate.**

Preliminary Results



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A picture is really worth 1000 words



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You should have already completed the work proposed in Aim 1.

- Reviewers and funders are risk adverse.
- They'd rather invest in a “sure thing.”
- You have to convince them that you can do the work and that you'll likely find what you claim you'll find.
- Most projects take longer than you think (and claim) they will take.

Approach

- Overall strategy, methodology, and analyses to accomplish the proposed specific aims.
- What you are going to do and how you are going to do it.
- How data will be collected, analyzed, & interpreted.
- Discuss potential problems, alternative strategies, and benchmarks for success of Aim achievement.
- If early stage project, describe strategy to establish feasibility & address high risk aspects of the work.

Introduction to the Methods

This study uses a multiple baseline, staggered entry, prospective cohort design with repeated measures. The study cohort will consist of anesthesia providers (AP; residents and CRNA) and PACU nurses (RNs) in two PACUs. Table 4 shows the baseline and intervention periods across the two study sites. In both MOR and VCH PACU there will be an initial 2-month baseline of field observations (actual patient handoffs). Then, RNs and APs from MOR will receive simulator-based handoff training with VCH clinicians receiving training starting 9 months later. Field observations will be obtained during a 2-month window after completing initial MOR training and before starting VCH training. At the end of initial VCH training (concurrent with an MOR refresher course), a final 2-months of field observations will be collected. In addition, training effectiveness will be assessed by videotaping and evaluating simulated handoffs. These evaluations will occur immediately prior to *and* after each subjects' initial simulation training. Later in the study, when MOR clinicians undergo their refresher training, there will be a second opportunity (immediately before the refresher course) for assessing a (9-12 month) post-intervention simulated handoff performance.

Traditional Methods Sections

- Experimental Design
- Data Collection
- Participants
- Data Management
- Recruitment/Training
- Data Analysis (and power analysis)
- Tools/Procedures
- Sampling strategy
- Experiments

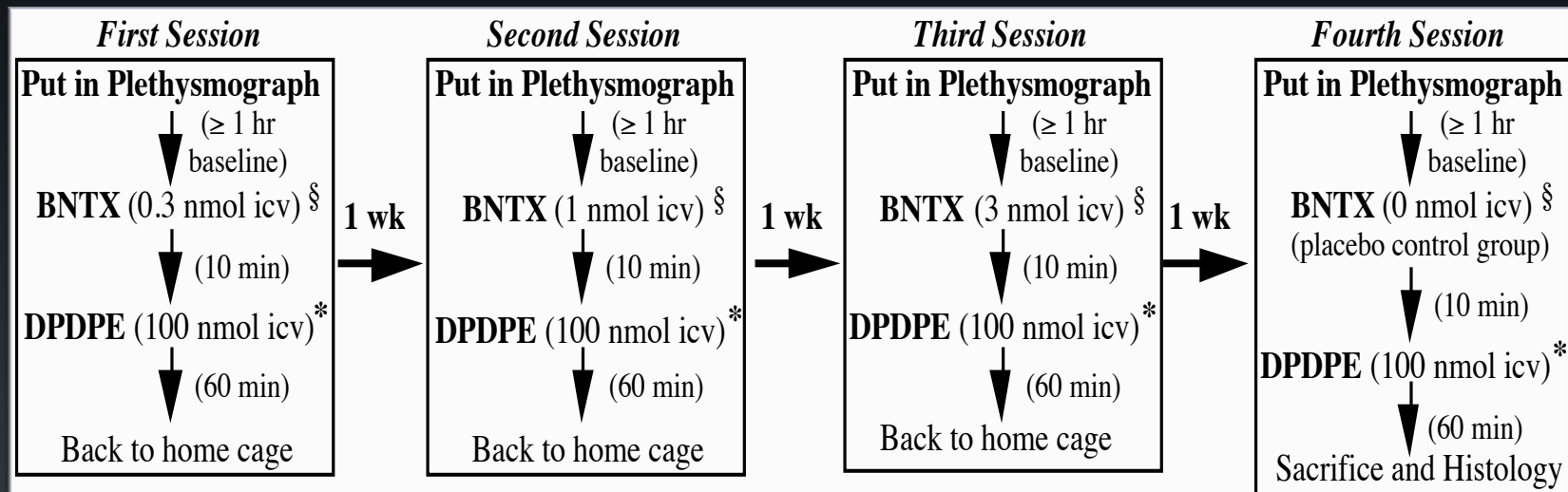
Details Matter

Study Environment

PACU (Type of cases)	# of OR's served	# of PACU beds	Annual PACU volume	# of PACU RN FTE	# of PACU RN on day shift	Nature of Handoffs
Main OR (MOR) (Quaternary care, burn, transplants, cardiac, neurosurgery and trauma)	19	20	12,620	41	10 <i>plus</i> 2 Charge RN	Primary RN accepts patient, others help as available. Circulating RN and surgeon not traditionally involved in handoff.
Vanderbilt Children's Hospital (VCH) (All types of pediatric cases)	14	28	12,372	46	10-11 <i>plus</i> 1 Charge RN	Primary RN accepts patient, others help as available. Charge nurse pre-fills some of PAR. Circulating nurse and/or surgeon always accompany patient to PACU and OR nurse is typically involved in the handoff.
Total	33	49	24,992	87	20-21+	

Details Matter

Experimental Design



\ast A fixed ED_{95} agonist dose is used throughout this four week experiment; different groups of rats will be studied after pretreatment with different antagonists (i.e., BNTX, NTB, or CTAP).

\S The antagonist dose changes each session, using a **Latin Square design**, such that an antagonist dose-effect curve is obtained from each rat studied (to permit calculation of the antagonist AD_{50}). Other rats in each antagonist dose group would have a different order of doses (e.g., BNTX 1, 3, 0, 0.3; BNTX 3, 0, 0.3, 1; or BNTX 0, 0.3, 1, 3).

Details Matter

Animal Usage

EXPERIMENTAL DESIGN		Desired Rats	Actual Rats	Average Yield
Specific Aim 1	To determine the neurobiological substrates for opioid receptor specificity in opiate-induced muscle rigidity.			
Experiment 1.	Mu opioid agonist (DAMGO) intracranial mapping study in opiate-induced muscle rigidity			
Initial dose-finding experiments				
10 sites / within-subjects' design / final 4 rats/grp @ ~70% yield = 6 rats/group		40	60	
Dose-effect curves at each site				
10 sites / within-subject's (3 doses 5 d apart) / final 8 rats/grp @ ~65% yield = 12 rats/grp		80	120	
10 sites/ within-subjects' control group (3 saline f/b alf) / 6 rats @ 80% = 8 rats/group		60	80	
Adjacent injections in active sites (2 cannula)				
7 sites / within-subject's (2 sites 5 dy apart) / final 8 rats/grp @ ~70% yield = 12 rats/grp		56	84	
Examine μ 1 effect at 4 most active sites				
4 sites / placebo or 2 NXZ pretreatment / final 6 rats/grp @ ~80% yield = 8 rats/group		72	96	
TOTAL RATS Experiment 1		308	440	70%

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Make it Easy for the Reviewer

- Give the reviewers the information they need when they need it (i.e., no flipping back & forth).
- Answer the reviewers' likely questions before doubt enters their mind.
- Don't raise questions/concerns without providing answers.
- Don't wash your dirty laundry in public.

Things to Consider Including

- Table of abbreviations (if a lot)
- Figure(s) for conceptual model
- Figure(s) of preliminary data
- Figure of planned experimental design
- Table of dependent and independent variables
- Gantt chart (project timeline) – often required

Focus on Readability & Understandability

Table 1. List of abbreviations found throughout this Proposal

ABA	American Board of Anesthesiology	HPS	Human-Patient (mannequin-based) Simulator
ASA	American Society of Anesthesiologists	MOCA	Maintenance of Certification in Anesthesiology
BARS	Behaviorally Anchored Rating System	OSCE	Objective Structured Clinical Examination
BCA	Board Certified Anesthesiologist	SDSE	Site Delivery Standardization Evaluation
(A)CRM	(Anesthesia) Crisis Resource Management	SEN	Simulation Education Network (of the ASA)
CRNA	Certified Registered Nurse Anesthetist	SME	Subject Matter Expert
FTR	Failure to Rescue	SP	Standardized Patient

Table 2. Developmental levels for the introduction of high-stakes simulation-based clinical competency testing

1.	Elements of good patient care clearly elucidated.	✓ 11,65,66
2.	Required skills or competencies articulated.	✓ 17,20,23,67
3.	Proof of concept demonstrated by measurement of skills or competencies (shown in trainees).	✓ 7,9,21,63,64
4.	Formative assessment of skills or competencies in trainees demonstrated.	✓ 7,9,28,61,62
5.	Proof of concept of assessment of skills or competencies in experienced personnel.	✓ 44,61,62,68
6.	Development of high-stakes examination tools, scoring rubrics, test administration protocols.	This Project
7.	High-stakes examination pilot-tested with experienced personnel; distribution of performance of “all-comer population” elucidated.	This Project
8.	Scaling up the examination (e.g., number and diversity of scenarios) to the appropriate number necessary for a reliable and accurate high-stakes clinical competency assessment process.	Informed by this project
9.	High-stakes examination results validated through comparison with other measures of experienced practitioner performance; possibly including real-world patient outcome measures.	Future work
10.	High-stakes examination qualified through “dress rehearsal” full-scale testing at multiple sites.	Future work
11.	High-stakes exam of experienced personnel proven through successful full-scale implementation.	Future work

Table adapted from Mankins ^{69,70}. Check marks (✓) indicate levels demonstrated by published research with samples cited.

Table of Study Variables

Table 5. Table of Preliminary Proposed Study Data Elements (only quantitative data fields shown*)

Data Element	Sub-Elements	Data Type	Categories or Range
Scenario		Categorical	1, 2, 3, or 4
Site		Categorical	1 through 10
Date of course		Date	00/00/00
Primary instructor ID #		Numeric	Random – 111-999
Participant ID #		Numeric	Random – 1111-9999
Participant role		Categorical	Hot Seat or First Responder
Participant demographics	Age	Numeric	25-70
	Gender	Categorical	Male or Female
	Race/ethnicity (<i>voluntary</i>)	Categorical	Caucasian, African-American, Asian, Hispanic, Native American, Other
	1 ^o ABA certification date	Date (year)	1960 to 2000
	Last ABA recertification	Date (year)	1985-2010
	Hours of billable care/wk	Hours	1-120
	Type of practice	Categorical	Academic, Private Group, Private individual, Military, Other
	% time doing own cases (vs. supervising others)	Percentage	0-100
	Subspecialty certification	Binary	Yes/No
	Focus of practice	Categorical	Primary types of cases performed [†]
Rater ID #		Numeric	1 – 9
Rater demographics	Initial rater ‘validation’	Date	00/00/00
	Days since last validation	Days	0 – 60
	Number of prior reviews	Numeric	0 – 60
Date of scenario scoring		Date	00/00/00
Medical/Technical scores [§]	Checklist items	Categorical	Present/absent. Also % of possible [§]
	Time (of rating)	Clock time	00:00 (military time)
	Global score	Categorical	1 – 7
Behavioral scores	Behavioral anchors [‡]	Categorical	1 – 7 [#]
	Time of rating	Clock time	00:00 (military time)
	Global score	Categorical	1 – 7
Overall performance score		Binary	Pass/Fail
Protocol Deviations		Binary	Significant deviations present/absent
SDSE (site standardization)	Fidelity checklist items	Binary	Present/absent. Also % of possible
	Global score	Numeric	0 – 100
ASA course evaluation	Evaluation questions ^{**}	Numeric	Average of participant scores (1 – 5)

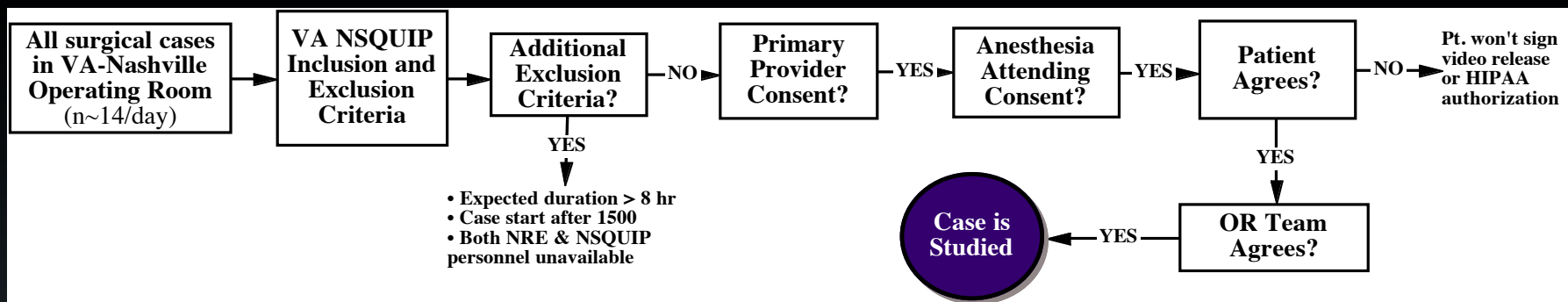
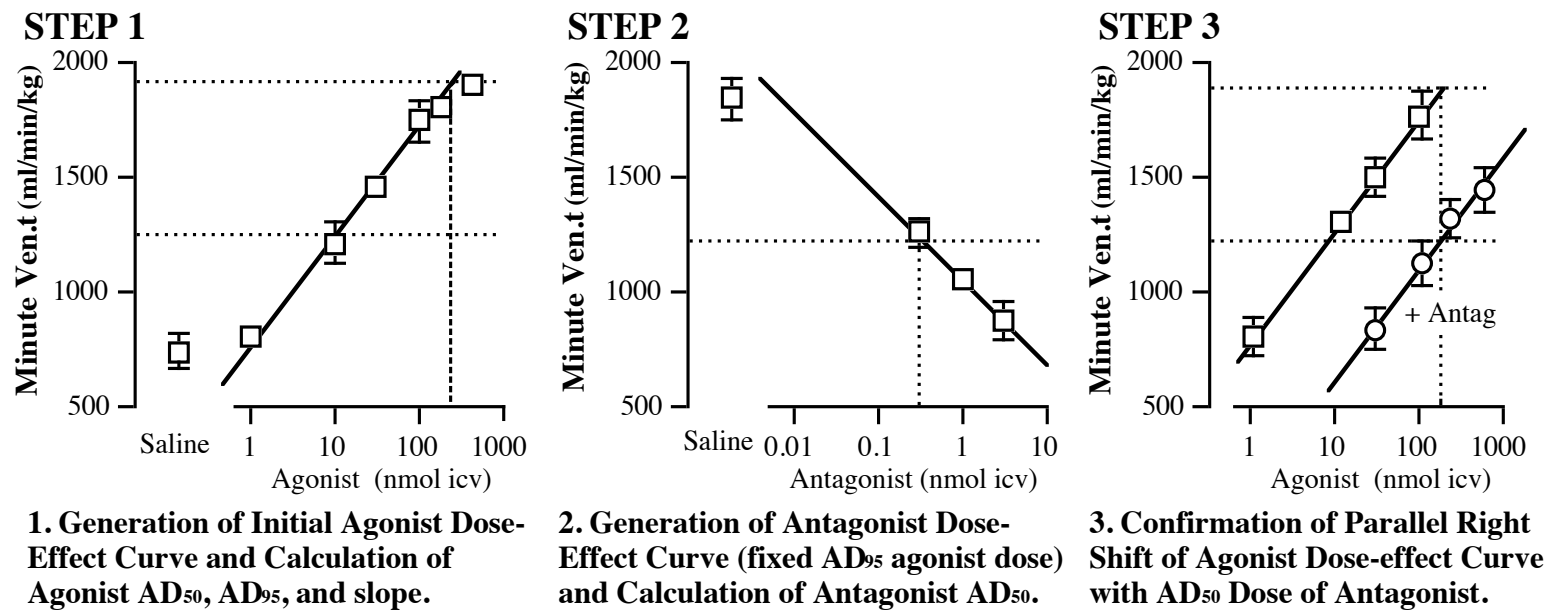


Figure 2. Proposed Experimental Design (depicted data are hypothetical)



Power Analyses

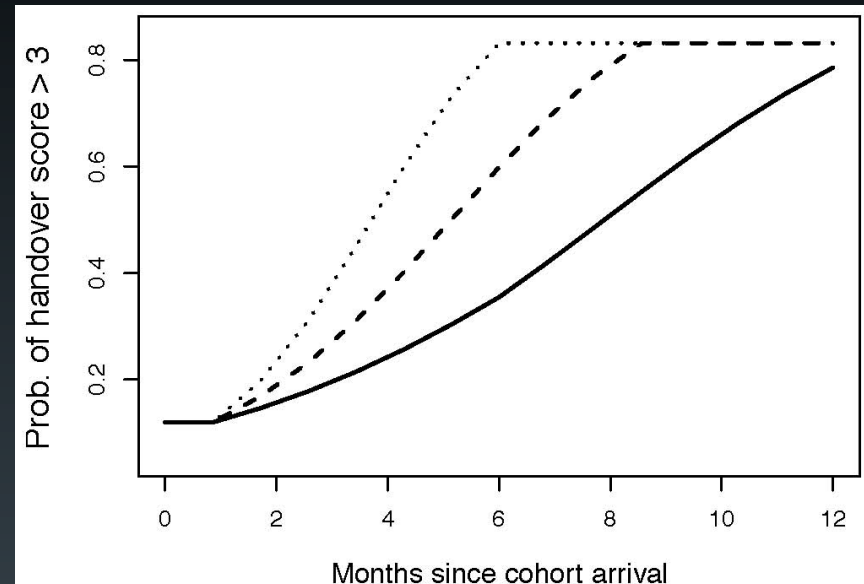
Table 8. Power Estimates [Dupont, 1990 #2318]

Aim	Comparison(s) (unit of analysis)	Sample Size §	Minimum Effect Size (in SDs)	
			80% power	90% power
SA 1	Immediate pre- vs. post-training (handoff)	100	0.28 *	0.33 *
	Delayed pre- vs. post-training (AP or RN)	50	0.57 †	0.65 †
SA 2	Baseline vs. Midway (MOR or VCH) ‡	72	0.47 *	0.54 †
	Pre- vs. post-STRAIT (both PACU)	144	0.33 *	0.38 *
SA 3	Combined effect (both PACU)	108	0.38 *	0.44 *
	Effect over time only in MOR	71	0.47 *	0.55 †
	Effect over time only in VCH	37	0.66 *	0.76 †

§ Sample size at each measurement time interval, except for SA1 which refers to the before & after training testing times.

‡ More conservative sample size assumption for the assessment of change in each site across the first two time intervals.

* 0.2 to 0.5 is a small to moderate effect size † 0.5 to 0.8 is a moderate to large effect size
[Cohen, 1988 #2317]. [Cohen, 1988 #2317].



Gantt Chart

Project Tasks	Year 1						Year 2						Year 3					
	01/11		05/11		09/11		01/12		05/12		09/12		01/13		05/13		09/13	
	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34
IRB approvals – <i>prior to start</i>																		
Study start-up meeting																		
Draft scenarios and rating tools																		
Assemble SME panel																		
Delphi Round 1																		
Delphi Round 2																		
Delphi Round 3																		
Pilot scenarios & create videos																		
Train raters																		
Assess rater reliability																		
Assess site delivery consistency																		
Data collection (MOCA courses)																		
Rater reliability reassessment																		
Data analysis																		
Face-to-face meetings at ASA																		
Face-to-face meetings at IMSH																		
Stakeholder Consensus Conference																		
Paper writing & dissemination																		



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Grantsmanship Pearl

What you say you will do is rarely what you will actually do

- Design and propose the best feasible project you can based on what you know at the time
- Be sure to discuss alternatives
- Once you get the grant, you will make every effort to meet the Aims but invariably in ways you didn't anticipate

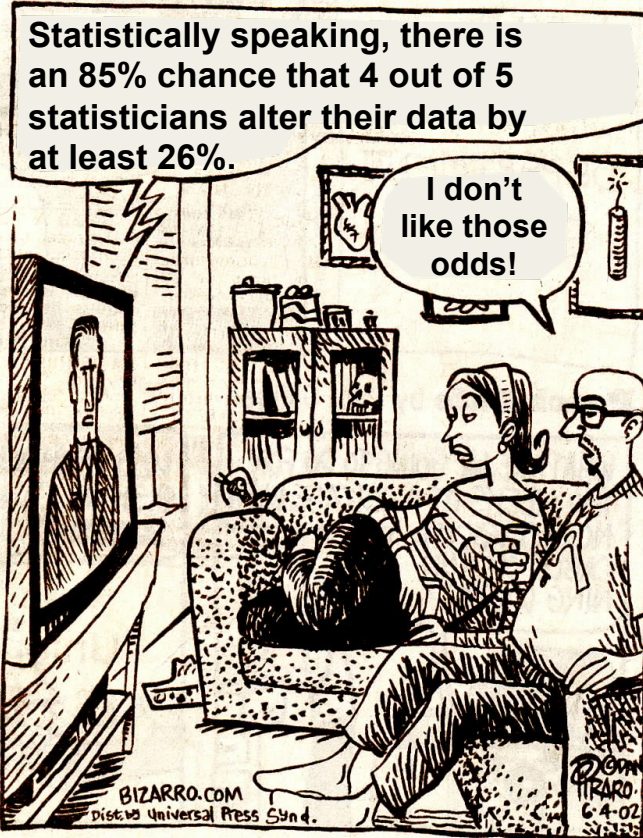
Grantsmanship Pearl

Parting Shots

- Become immersed in your grant – ignore everything else that you can.
- An experienced PI will spend at least 200 hours writing a new grant
- Use the grant writing process to refine and improve your science
- Make it fun!

Questions?

Bizarro by Dan Piraro



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