Experimental study design and grant writing in eight steps and 28 questions

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While writing a grant proposal may take a few days, the planning of the study takes much longer and requires thoughtful consideration. The use of a systematic and itemised approach can help in planning crucial details of a study. An eight-step, 28-question, iterative approach is proposed to help with the careful planning of experiments in order to maximise the researchers' chances of acceptance when submitting the study for funding and its results for publication. The steps include defining a relevant research question; selecting instrumentation, study design and statistics; determining sample size and sampling procedure; ensuring data quality throughout data collection and analysis; setting personnel and budget requirements, and writing a convincing grant proposal. Reviewers pay particular attention to the importance of the research topic and question, the presence of a clear problem statement and up to date review of the literature, the use of an optimal design and instrumentation, a sufficient and unbiased sample, and appropriate and well applied statistics. They also appreciate a clear and easy to follow proposal. The research question is the keystone of the entire enterprise, followed by the selection of an optimal study design and the control of possible confounding variables. No study is perfect. The researchers must constantly weigh advantages and disadvantages and select the most scientifically sound and feasible alternatives. While the steps and questions presented are best applied to experimental studies, the principles are also applicable to a wide range of questions and observational, evaluative and qualitative designs.

Keywords research design/*standards; financing, organised/methods; data collection; ethics; writing/standards.

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Introduction

Preparing a study and writing a research grant proposal are complex undertakings, not only because of the numerous elements that go into the design and the proposal, but also because each element plays a crucial role in the success of the enterprise. For example, a study can address an important and relevant educational question, but if the sampling procedure is biased or the sample size too small, then the entire study is compromised, possibly to the point of being fatally flawed. We propose a systematic eight-step, 28-question approach to experimental design and grant writing that should help in keeping track of all the crucial elements of the process and in ensuring the quality of the study. The steps and questions are summarised in Table 1; the table can be used as a checklist to ensure the completeness of the study proposal. Each step will be discussed and examples presented. Bordage recently analysed the nature of the comments written by external reviewers when evaluating medical education research manuscripts submitted for publication.[1] Special attention will be paid in presenting the study design steps and questions to highlight the strengths and weaknesses that were noted by the reviewers. Nearly half of the top 19 reasons given by reviewers when accepting or rejecting manuscripts need to be addressed at the design phase of a study in order to avoid unpleasant surprises or unfavourable reviews. The reasons, stated positively, included: the study addressed an important problem; the introduction contained a clear problem statement and a critical and up to date review of the literature; the researchers used an optimal design and instrumentation; the study contained a sufficient and unbiased sample, and the statistical analyses were appropriate and optimal. While the steps

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Key learning points

The research question and study design are the two most important components of a study.

Outcomes of interest dictate instrumentation, not the other way round.

Statistical consultation may be a wise investment.

Too few subjects can lead to erroneous conclusions. Too many subjects can lead to trivial conclusions or waste of resources.

Funding agencies look for studies that are important and relevant to their mission, scientifically sound, conducted by capable researchers, and reasonably priced.

Well written and easy to follow proposals will impress reviewers and facilitate their work.

Study design and grant writing require time and much iteration. Plan ahead.

and questions are best applied to experimental studies, many of the principles presented are also applicable to a wide range of questions and designs, including observational, evaluative and qualitative studies.

Step 1: The research question

1 What topic (idea) of study are you interested in?
2 What has already been done in this area? (The literature.)
3 What major outcome(s) (dependent variable) are you interested in?
4 What intervention (independent variable) are you interested in?
5 Are you looking for differences or a relationship (association)?
6 To what group (population) do you wish to apply your results?
7 What is your specific research question?
8 What answer do you expect to find to your question? (The research hypotheses.)
9 Why is this question important today? (Relevance.)

Table 1 Research design and grant writing in eight steps and 28 questions

Steps	Questions
1 Research question	1 What topic (idea) of study are you interested in?
	2 What has already been done in this area? The literature.
	3 What major outcome(s) (dependent variable) you are interested in?
	4 What intervention (independent variable) are you interested in?
	5 Are you looking for differences or a relationship (association)?
	6 To what group (population) do you wish to apply your results?
	7 What is your specific research question?
	8 What answer do you expect to find to your question? The research hypotheses.
	9 Why is this question important today? Relevance.
2 Instrumentation	10 Will you use an existing instrument, modify one, or develop a new one?
	11 What are the psychometric qualities of the scores?
3 Research design	12 Do you want to intervene or simply observe?
	13 Do you need a control group?
	14 How will you control for confounding variables?
	15 What is the 'best' research design to answer your question?
4 Statistics	16 Which statistical method is optimal?
5 Sample	17 What are your criteria for inclusion and exclusion of subjects?
	18 How are you going to obtain your subjects?
	19 If an experiment, how will you assign the subjects?
	20 How many subjects do you need? Power.
6 Data collection and quality	21 How are you going to collect data and monitor the quality?
7 Timetable and budget	22 What is the timetable? Schedule.
	23 Who will be doing what? Personnel.
	24 What equipment and materials will you need?
	25 How much will it cost? Budget.
8 Protocol and grant proposal	26 How will you keep track of the study? Research protocol.
	27 What is the granting agency interested in funding? Grant proposal.
	28 What forms and application process will you follow?

The single most important component of a study is the research question.[2] It is the keystone of the entire enterprise. Everything hinges on the quality of the research question, hence its crucial importance. Two of the initial challenges in designing a study concern selecting a relevant topic and going from a topic to a researchable question. The top reason given by reviewers for accepting manuscripts was the fact that the researchers had addressed a timely and important question. Relevance is multifaceted and goes beyond simply addressing issues that are germane to the mission of the funding agency, although that is clearly important. It also refers to practical implications, methodological advances and theory building. The researchers need to show in a convincing manner that their proposed study represents a step forward and that the eventual results will be worthwhile and will contribute to the literature and the field. A focused, thoughtful and critical review of the literature will help build a cogent problem statement and a clear research question. A strong conceptual framework will further solidify the proposal. The problem statement and question should be neither too narrow nor too broad or unfocused. Simplistic questions will likely yield trivial results, while broad questions may not be researchable.

Consider the following research question and its basic elements (noted in parentheses). Do medical students who take lectures from basic science instructors (*target population*) who attended workshops on interactive lecturing skills (*intervention: first level of the independent variable*) obtain different (*nature of the relationship: difference between the two levels of the independent variable*) end of semester examination scores (*outcome: dependent variable*) than those whose instructors viewed video demonstrations of the skills (*intervention: second level of the independent variable*)? Of the four elements of the research question – independent and dependent variables, relationship between variables, and population – the last two are often left unclear. The nature of the relationship is crucial to selecting optimal data analyses and drawing appropriate conclusions. Is the issue to compare performance between training programmes, for example, workshops and video demonstrations, by establishing a difference? Or do the researchers want to determine the level of association between, for example, the amount of interactions and student performance? Is the study about differences or associations, or both? Furthermore, are the outcome (dependent) variables sufficiently operational to be observed or measured? General concepts (e.g. lecture skills) are too vague and can lead to too many interpretations. The researchers need to define the precise aspects of the concept they want to address. For example, in the case of lecture skills, are they concerned with the quality of the learning objectives, the communication skills of the lecturer, audience participation, the quality of the audiovisual aids, or student satisfaction or performance? The precise nature of the outcomes and their relationships among variables will dictate the data analyses and the type of conclusions that can be drawn. Finally, to whom do the researchers want to apply (generalise) their results? Researchers need to differentiate between the population of interest, that is, those to whom they want to generalise their findings, and the sample, those who will participate in the study. Much of educational research is carried out on convenience samples or static groups that may have limited generalisability, either from a statistical perspective or an argumentative point of view. The researchers need to keep the generalisability of their findings in mind when choosing subjects for the study and justify their sample selection and sampling method to the reviewers (and eventual readers).

Operational variables and clearly stated relationships and the population contained in the research question lead in turn to clearly stated research hypotheses, that is, the anticipated results. For example, the descriptive hypothesis may be: 'It is hypothesised that students who take lectures from basic science instructors who attended workshops on interactive lecturing skills will obtain better end of semester examination scores than those who take lectures from instructors who viewed video demonstrations.' The conceptual framework used to formulate the question and the hypotheses could come from learning and instructional theories whereby students, and in this case instructors as students, are expected to learn more when actively involved in the teaching/learning process. Not only will the hypotheses guide the research design and data analyses but they will also begin to alert to possible confounding variables (i.e. alternative explanations) that need to be addressed at the design phase of the project. The importance of the research question and related issues cannot be emphasised enough. The research question will dictate the remaining elements of the study. The question needs to be stated early in the proposal, possibly in the very first sentence or paragraph, and described and justified in sufficient detail. Errors or oversights at this early phase of the study will be costly later on.

Step 2: Instrumentation

10 Will you use an existing instrument, modify one or develop a new one?

11 What are the psychometric qualities of the scores?

Once the outcome variables are clearly defined, the researchers then select an appropriate, ideally optimal, instrument to measure the outcomes of interest. A common error is to select instruments on the basis of convenience, such as readily available test scores rather than an instrument directly related to the precise nature of the desired outcome; for example, selecting test scores on the behavioural science portion of a national examination to measure communication skills in difficult clinical situations rather than using more appropriate standardised patient ratings. The outcomes dictate the instruments, not the other way around. While some instruments may be readily available and appropriate, others will need to be modified or developed *de novo*. Using existing instruments is desirable whenever possible, because their psychometric qualities (e.g. reliability and validity) will already be established and it may be possible to compare the findings with those from other studies. If instruments are either modified or developed, the psychometric qualities of the scores derived from the instruments should be addressed and any shortcomings or limitations discussed. The administration procedures, measurement scales (i.e. nominal, ordinal, interval or ratio scales) and scoring methods need to be clearly stated in order to assess the validity of the measures and the interpretation of the results to come.

Step 3: Research design

12 Do you want to intervene or simply observe?
13 Do you need a control group?
14 How will you control for confounding variables?
15 What is the 'best' research design to answer your question?

The second most important component of a study is its design, that is, the means the researchers will use to answer the research question. Selecting an optimal design and controlling for possible confounding variables (i.e. alternative explanations than those intended) represent two main challenges facing the researchers. Educational research is often conducted in naturalistic settings that may carry threats to the validity of the study, such as loss of subjects, selection bias, historical events or maturation (see Frankel & Wallen[3] for a discussion of strong versus weak designs and threats to validity in educational research). The researchers need to make a convincing argument about the appropriateness of the design chosen, given the particular circumstances of the study. They also need to demonstrate that potential confounding variables have been considered and controlled as far as possible, either by design (e.g. counterbalanced groups in the case of multiple interventions or stimulus material) or by post hoc analyses (e.g. repeated measures or analysis of covariance), or both. A convincing argument can be made by comparing alternative designs and showing why one design was chosen over another.

Step 4: Statistics

16 Which statistical method is optimal?

The leading reason given by reviewers for rejecting manuscripts was inappropriate, suboptimal or incomplete statistical analyses.[1] The proper use of statistics comes from the careful consideration of the number and type of variables involved, the nature of the relationship between the variables (as expressed in the research hypotheses), and the design.[4,5] Using the simplest statistical methods that do the job leads to the most straightforward conclusions. Easy access to statistical packages can lead novice researchers (or amateur statisticians) to select inappropriate statistics or apply them incorrectly. This is also the point at which confounding variables that cannot be controlled through the study design need to be evaluated, using methods such as analysis of covariance (ANCOVA) or multiple or logistic regression. Statistical consultation may be a wise investment. Well thought out and unique approaches to data analysis were praised by reviewers.

Step 5: Sample and sampling

17 What are your criteria for inclusion and exclusion of subjects?
18 How are you going to obtain your subjects?
19 If the study involves an experiment, how will you assign the subjects?
20 How many subjects do you need? Power.

Sampling procedures, inclusion and exclusion criteria, and assignment of subjects are critical aspects of a study in terms of avoiding biases. In addition, having the appropriate number of subjects (power calculations or tolerance analyses) is critical, not only for drawing appropriate conclusions, but also for maximising resources. Too few subjects can lead to erroneous conclusions, while too many subjects can lead to trivial conclusions or waste of precious resources, an issue especially dear to funding agencies. Several excellent sample size estimation computer programs are now available, either as stand-alone programs (e.g. nQuery™) or integrated to statistical packages (e.g. SPSS™, NCSS™, EpiInfo™). It is wise to consult a statistician for help when determining the number of subjects before the study is begun. Appropriate samples,

adequate sample sizes and clearly described subjects were praised by reviewers.

Step 6: Data collection and quality control

21 How are you going to collect data and monitor the quality?

Data entry procedures and quality control measures need to be presented in sufficient detail to convince reviewers that the integrity of the study will be maintained. Special attention needs to be paid to training observers and to detecting possible biases that may appear during the study such as selection biases or loss of subjects. Data quality needs to be monitored throughout data collection and data analysis. Tasks and personnel need to be described clearly.

Step 7: Timetable and budget

22 What is the timetable? Schedule.
23 Who will be doing what? Personnel.
24 What equipment and materials will you need?
25 How much will it cost? Budget.

Who will do what and when? What equipment is needed and how much will it cost? The level of detail provided in the proposal will vary depending on the guidelines of the funding agency. For example, some agencies will require itemised budgets, while others ask only for global budgets. In any event, it is useful to organise the schedule and the budget according to five main phases of a project: initial preparation (getting started); pilot testing of instruments and procedures; data collection; data analysis and interpretation, and dissemination of the results, including report and manuscript preparations and presentations at conferences. Within each phase, the activities can be presented in a four-column table indicating when (date), what (task), who (personnel) and how long (duration) each activity will take.

Step 8: Protocol and grant proposal

26 How will you keep track of the study? Research protocol.
27 What is the granting agency interested in funding? Grant proposal.
28 What forms and application process will you follow?

With all the study elements in hand, it is time to write the research protocol and the grant proposal. While the research protocol and the grant proposal share a lot of the same information, they can be slightly different. The proposal is addressed to the granting agency in order to obtain funding. It is intended to market the study and convince the reviewers and the agency to fund the project, while the protocol may be more procedural. The protocol contains the set of instructions and procedures to be implemented throughout the study. It will serve as a constant reminder of things to do. Otherwise, and to paraphrase Mager[6] about learning objectives, the researchers may find themselves elsewhere without knowing it!

Funding agencies will typically ask four basic questions about the proposed study.

Firstly, is the topic (research question) germane to the mission of the agency? For this they will look at the title, the abstract, and the statement of relevance.

Secondly, is the study scientifically sound? They will look at the research question and hypotheses and the research design and sample size. They will also make sure that ethics approval (IRB: Institutional Review Board) was sought.

Thirdly, are the researchers capable of conducting the study? They will look at the researchers' training and past experience, the level of institutional support and the breadth of the study.

Fourthly, how much will it cost? This concerns the budget and timetable.

When a committee reviews a proposal to decide on funding, typically only two or three committee members read the entire proposal along with the external reviewers' evaluations. The other members will rely mostly on the title, summary, budget, schedule and external reviews. Thus, the importance of the summary cannot be overemphasised and will be addressed in more detail later in this paper. The review criteria used by reviewers of grant proposals largely mirror the criteria used for research manuscripts submitted to journals. (For an analysis of the criteria, see the Report of a Joint Task Force on Review Criteria for Research Manuscripts.[7])

The type of information and the level of detail in the grant proposal will vary depending on the guidelines provided by the funding agency. Researchers should pay careful attention to the specific instructions and requirements of the funding agency to which the proposal will be sent for review. Some agencies will simply return incomplete or unorthodox proposals. Don't confuse the reviewers by deviating from the norms and guidelines. A well written and easy to follow abstract and proposal will impress reviewers. A set of generic guidelines for preparing a grant proposal (modelled in part (with permission) on the National Institutes of Health application forms[8]) is presented in Table 2 under 10 major headings: title page, summary page, key personnel, budget for the first year, budget for the remaining period of support, budget justification, resources, research plan, literature cited, and ethics.

Table 2 Guidelines for preparing a research grant proposal*

1	Title page
1·1	Title of proposed study (see maximum number of characters allowed by agency)
1·2	Principal investigator: name, degree(s), position title (rank), department, mailing address, e-mail, telephone, fax
1·3	Human subjects: Yes/No
1·4	Ethics approval: Yes/No/Pending
1·5	Dates of proposed period of support: from (mm/dd/yy) to (mm/dd/yy)
1·6	Total number of months
1·7	Cost for first year of support (first 12 months): Direct and indirect (administrative)
1·8	Cost for total project: direct and indirect
1·9	Administrative official to be notified if award is made: name and address
1·10	Signature of principal investigator
1·11	Signature of administrative official
1·12	Date
2	Summary page Structured format (see maximum number of words allowed by funding agency) List of key words (six maximum)
2·1	Objectives (research question and hypothesis)
2·2	Background and significance
2·3	Design
2·4	Target and sampled population; sample (including size) and sampling
2·5	Outcomes
2·6	Intervention
2·7	Anticipated results and conclusion (see descriptive hypothesis(es))
2·8	Schedule and personnel
3	Key personnel
List of key personnel (principal investigator, co-investigators, research assistants, and consultants) and for each person include (if applicable) name, position (rank), education/training (institution, location, degree, year(s), field of study), certification and licensure, number of peer-reviewed publications (including maximum of six main journal references), number of research grants (past and present, including title, funding agency, amount and period of support)	
4	Detailed budget for first year of support
4·1	Personnel: name, role, percent time, salary requested, fringe benefits, total
4·2	Consultant(s)
4·3	Equipment (itemise)
4·4	Supplies (itemise)
4·5	Subject cost (participation stipend)
4·6	Travel (for study purposes and for presentation at conferences)
4·7	Other expenses (itemise)
4·8	Total direct cost
4·9	Total indirect (administrative) cost (if applicable)
4·10	Combined total direct and indirect cost
5	Detailed budget for remaining period of support (see 4 above)
6	Budget justification (each item in the budget must be justified)

Table 2 Continued

7	Resources Facilities and equipment to conduct the study, including local support
8	Research plan (see number of pages allowed by funding agency)
8·1	Problem statement, specific aims and research question(s)
8·2	Background (including review of literature) and significance
8·3	Intervention and outcomes
8·4	Instrumentation
8·5	Research hypothesis(es)
8·6	Research design and confounding variables
8·7	Data analysis
8·8	Target and sampled population, sample (sample size) and sampling
8·9	Data collection and quality control
8·10	Schedule (in months, according to five main project phases: preparation, piloting of instrument and procedures, data collection and quality control, data analysis, and dissemination (report, abstracts, journal articles)
9	Literature cited (only; not a bibliography)
10	Ethics (ethics approval and consent forms)

* Modelled in part (with permission) on the National Institutes of Health (NIH) Application for a Public Health Service Grant, Office of Extramural Research, US Department of Health and Human Services.

Tables 1 and 2 can be used as checklists to ensure completeness of the proposal and study elements. A well prepared proposal constitutes a worthwhile investment for the publication manuscripts to come. The details of the study are freshest in the researchers' minds at this point.

Proposal guidelines

Title

The very first element of the proposal, its title, is an important marketing device. It sends a clear message to the readers as to your focus and intention. The key words should resonate well with the funding agency's mission. View the title as the shortest possible abstract where both topic and importance are highlighted (see Huth's[9] indicative and informative components). For example: *Interactive lecture skills for basic science instructors: are workshops more effective than demonstration videos?* The title should capture the attention of the funding agency and the reviewers, while remaining commensurate with the scope of the study. One of the reasons given by reviewers when rejecting manuscripts was misleading titles. You want to be able to deliver the product announced in the title.

Summary

The importance of the summary was mentioned earlier, especially because it is one of the only elements of the proposal that is carefully read by all involved in deciding whether or not to fund the proposed study. A structured abstract format can serve as an advance organiser and a useful means of preparing a comprehensive summary.[10] The elements include: objectives, background and significance, design, target and sampled populations, outcomes, intervention, anticipated results and conclusion, and schedule and personnel. The results and conclusion sections of the structured abstract are used to present anticipated results (the descriptive hypotheses) and to highlight their importance for the granting agency, the institution and the field.

Key personnel

The next section contains thorough, yet concise, information about the principal investigator and other key personnel involved in the study, including co-investigators, research assistants, programme co-ordinator, support personnel and consultants. Funding agencies do not want detailed and lengthy curriculum vitae. A one or two-page biographical

sketch is usually sufficient; agencies want to assess the information quickly. The reviewers are looking for key information about the researchers' credentials and experience. They want to know about each person's education, training and appointments, along with the number of grants obtained (past and current), the number of peer-reviewed publications, and a short list of full journal references germane to the proposed study. This information will be used by the reviewers to judge whether or not the researchers are capable of conducting the proposed study in a satisfactory manner, both scientifically and administratively.

Budget

The budget is addressed in three separate sections, namely the budget for the first year of support, the budget for the remaining period of support, and budget justification. By separating the first year budget from the remaining period, the funding agency can readily assess the budget allocations needed for the coming fiscal year. While some agencies require detailed budgets, others will simply require global budgets. In either case, it will be useful for the researchers to have a detailed breakdown of their budget, especially for estimating total costs while planning the budget and for keeping track of monthly expenditures during the course of the study.

Budgeted items include personnel, consultants, equipment, supplies, subject costs for participation, travel expenses related to the project itself and to present results at conferences, miscellaneous expenses (planning the unexpected) and indirect administrative costs. Some funding agencies may restrict the type of expenditures allowed. For example, some may not allow or limit indirect administrative (overhead) costs, while others may not allow the purchase of certain types of equipment such as computers. Be sure to follow the rules and regulations of the agency. If the study is large or very expensive, consider breaking it into phases that can be funded sequentially, based on interim reports.

Resources

The section on resources addresses the need for adequate facilities and equipment to conduct the study, either through existing resources or with resources to be included in the budget. Items to consider include space, computer equipment and data processing resources. The researchers can also use this section to refer to letters of institutional support from key stakeholders, such as deans, department heads or programme directors. Each person can highlight the uniqueness and importance of the study and their willingness to participate. The researchers can prepare draft letters to facilitate the process. The final letters can be announced in this section and copies included in appendices to the proposal.

Research plan

The research plan is the very heart and soul of the proposal. It contains the detailed description of the study, from problem statement and research question, to data collection and analyses, to scheduling and timetabling. The subsections are similar to those used for the structured abstract. A parallel structure between various sections of the proposal will facilitate reading by the reviewers. Most funding agencies impose a maximum page limit for this section, such as 10 or 25 pages. It is important to follow these precise instructions. Failing to do so can be cause for technical rejection.

Writing

Clear and straightforward writing will be appreciated by the reviewers. They don't like to spend time second guessing researchers or trying to find their way through a maze of details. The logic should be easy to follow from one section to the next. Terminology should be uniform throughout the proposal. Changing terminology, for example, from groups to programmes when both have the same meaning, will confuse the reviewers. Use a spellchecker and have one or two colleagues who are not involved in the study proofread the final draft.

Literature cited

The penultimate section contains the list of references cited in the proposal. This should not be a bibliography of all the literature considered by the researchers. It simply contains the key references cited in the proposal. The researchers want to show that they know the field and that they are positioning their proposed study in such a way as to make a significant contribution. More references are not necessarily better. A focused and critical review of the literature will score more points with the reviewers than an indiscriminate listing of references. The researchers should keep in mind that some of the reviewers will know the literature in great detail.

Ethics

Ethical approval of the study by the institution's ethics committee is becoming an essential component of educational research, required by funding agencies and

publication journals.[11–13] The purpose of ethics approval is to protect human subjects and their records by assessing risks and benefits, unbiased selection, confidentiality and incentives to participate. When informed consent is sought, a copy of the informed consent form should be included in an appendix to the proposal. The main elements of the informed consent form include presenting (in lay language) the goals of the study (without inducing experimenter bias), risks and benefits, alternatives to participation, confidentiality, rights of the subjects, and the name(s) of person(s) to contact about queries or for dropping out. Usually ethics approval has not been obtained at the time of making the proposal. If this is so, simply indicate that ethics approval is pending (see item 1·4 on title page in Table 2) and send a copy of the approval letter when it becomes available. Remember that ethics approval needs to be obtained *before* data collection. Ethics committees do not approve studies retrospectively.

The same ethical principle that forbids dual submission of manuscripts to journals also applies to grant proposal submissions. However, some agencies will allow dual submission when duly informed, with possible cost sharing or preferred selection.

Funding agencies

Funding agencies can be considered from various geographical aspects such as local, state or provincial, national and international. Local sources include institutional and citywide sources such as young investigator grants, foundations and community trusts, curriculum development grants and summer student programmes. The personnel in the institution's grants and contracts office and public relations office are useful people to consult because they know broad networks of resources. State funding includes state licensing boards (for evaluation projects) or state professional associations. National and international agencies include government sources (e.g. departments of education and health, bureaux of manpower, and health institutes), foundations, educational and professional organisations (e.g. licensing authorities, medical school associations) and pharmaceutical and other proprietary companies.

Preparing a study and a research proposal is not as linear as the eight steps and 28 questions may imply. It is an iterative process in which the researchers gradually hone in on a topic and a research question and constantly weigh the advantages and disadvantages of various designs and instrumentation. It often brings the researchers back to reconsider previous decisions and, at times, to take new directions. For example, a measurement problem can force the researchers to select different outcomes, or sample size requirements may preclude certain interventions because there are not enough subjects available. The more thinking and discussion that go on during the design phase of a study, the less likely it is that unexpected events will occur or fatal flaws show up.

While writing the grant proposal may take a couple of weeks, detailed and thoughtful planning of the study takes much longer. Four to 6 months is not unreasonable. No study is perfect. Study limitations, such as less than ideal designs, confounding variables, sampling biases or imperfect instrumentation, need to be considered and addressed very early on in order to avoid rejection at the funding level, or worse yet, at the publication level. Prevention through the use of a systematic and itemised approach should pay off, for both the researchers and the scientific community as a whole.

Contributors

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