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## Chapter 8 Preparing grant applications

### 1. Introduction to preparing grant applications

Research funding agencies want to support outstanding researchers to conduct cutting edge studies to advance knowledge that contributes to the solution of health problems. Applicants for grants must convince the funding agency that they are high-quality scientists whose research proposal addresses important question(s) and that the studies planned will deliver the answer(s) on time and within budget. Research proposals have many common elements, but, in intervention trials involving human subjects, some critical aspects, such as ethical, legal, and social issues, must be addressed particularly carefully in the grant application. Determination, good planning, and meticulous attention to details are essential for a successful application.

### 2. Grant awarding agencies

There are many national and international funding agencies that include intervention trials in their funding portfolio. These include, but are by no means limited to, the WHO Tropical Diseases Research Programme, the European and Developing Countries Clinical Trials Partnership, the Bill and Melinda Gates Foundation, the UK Medical Research Council, the US National Institutes for Health, the Wellcome Trust, the Volkswagen Foundation in Germany, and the French Institut National de la Santé et de la Recherche Médicale (INSERM). The pharmaceutical industry and several non-governmental public–private partnerships created in the last decade have partnered with academic institutions in the development of new drugs and vaccines for LMICs, including supporting clinical trials. In addition, some government development agencies, such as United States Agency for International Development (USAID) and UK Department for International Development (DFID), also support studies on the evaluation of public health interventions.

#### 2.1. Understand the remit

All funding agencies have their own specific remits and priorities. Even for intervention trials, some agencies have specific programmes for particular diseases or will only support certain kinds of study. It is imperative to be familiar with the remit of the agency to which a funding application is planned and to understand what they expect from supporting a research proposal; otherwise, a lot of unnecessary time can be wasted by applicants.

Many funding agencies will ask why they, rather than some other group, should support a specific trial. For example, for a trial of a new vaccine that has been developed by a pharmaceutical company, a likely question is why the company is not providing the support, as it will stand to benefit if the vaccine is found to be efficacious.

#### 2.2. Early contact

Those wishing to conduct a specific trial must decide on the most suitable funding agency to approach for support. One sure way of ensuring that a particular funding agency is an appropriate recipient of an application is to make early contact. Most agencies have detailed information on their websites where information about the forms of support offered, the application process, and deadlines for applications are available. Where there is uncertainty, it is always a good idea to contact individual officers in the agency. They usually welcome an early opportunity to discuss a potential applicant's plans, and they will suggest the best way to submit a grant application. Importantly, they will advise if the agency is unlikely to support a particular application (for example, because the topic is outside of their remit or priorities). Such information early in the process of seeking a grant may be invaluable. A common mistake is to leave the preparation of an application and contact with the grant agency until close to a deadline. Plan ahead, and leave plenty of time for discussions with the grant agency's officers and to prepare an application. A rushed application is almost always a poor one. Many funding agencies will offer to look at an outline application, sometimes known as a letter of intent or a concept note, to advise on whether or not it is within their remit or how it might be modified to better fit their funding schemes.

### 3. Grant types

The type of support needed for an intervention trial depends on the personal and institutional circumstances of the applicants. For example, an applicant in a tenured position in an academic institution may not require salary support but just need direct and indirect research project costs for equipment, staff, materials, and administrative costs. If the principal applicant is not in a salaried position, salary support will be needed, in which case, for some funding agencies, a fellowship may be an appropriate avenue of support.

### 3.1. Project and programme grants

In the parlance of many funding agencies, a *project grant* is for a specific piece of work to answer just one or two specific questions, usually for a period of about 3 years. It may be, for example, a clinical trial to test the safety of a drug in its early development phase. A *programme grant* is for a larger, more complex set of studies to answer several related questions and is often for 5–7 years. A clinical trial may sometimes form part of an application for programme grant support. Some agencies may not support project or programme grants but only fellowships, or vice versa, so it is important to check this early.

Once a grant has been awarded, in most cases, funds are released on a yearly basis, taking into account technical progress and financial implementation. Estimating the cost of a project can be a very complicated exercise, especially with respect to indirect costs associated with the study. These aspects are discussed in Chapter 18.

### 3.2. Personal fellowships

Personal fellowships are for researchers who do not have a salaried, tenured, or substantive ‘permanent’ position. Fellowship applicants request for their personal salary, in addition to partial or complete research costs. Many agencies have programmes to support scientists throughout their career, from the Masters/PhD stage through one or more intermediate phases where they establish their independence, and finally to senior levels.

### 3.3. Special initiatives

Investigators should be on the lookout for special initiatives such as calls for support to conduct a trial on a particular topic. When there is a special initiative, research proposals are competing within a smaller specified area of science, and applicants are likely to be reviewed by people who work in roughly the same subject area.

It is not unusual that large clinical trials are conducted as a collaborative effort. For example, vaccine trials might have to be conducted in multiple sites and countries where there are significant differences in population structure, host genetic factors, public health systems, environment, and prevalence of co-infections. In this case, it may be important to collaborate and coordinate approaches to more than one funding agency.

## 4. Grant awarding process

### 4.1. Peer review

Nearly all funding agencies subject applications for support to some form of independent peer review. Usually, this will take the form of soliciting comments on the proposal from scientific experts. Some will be selected for their expertise in scientific areas included in a proposal, while others may be chosen for their broad experience to give a generalist perspective. Thus, the application should include a balance of appropriate details and a broader vision, as the familiarity of those conducting the review with the subject area may vary.

Most agencies do not reveal the identity of independent reviewers, so that they provide frank objective comments, including for applications from persons they know or are known by. Agencies sometimes solicit suggestions from applicants as to who might review a proposal, although they may choose not to use anyone suggested. On rare occasions, applicants request that certain individuals not be asked to review their application. This may be because of potential conflicts of interest or because the applicant considers that the individuals may not be objective. Funding agencies do try to take such requests into consideration in their choice of reviewers.

Most agencies allow applicants to see the anonymized reviews or extracts from them, in which reviewers will usually highlight strengths and weaknesses of a proposal. These comments may be sent either after a funding decision has been made or to applicants requesting a response before the funding decision is made. Policies vary from agency to agency. If applicants are given the opportunity, they should always respond carefully and concisely to criticisms or

suggestions made by referees, as both the referees' reports and the response to them will be considered by the panel that makes the final funding decision (see Section 6).

It is common that the review process is conducted in two stages. Some agencies recommend that the applicants first submit a 'letter of intent' that gives a brief description of the proposed research. The agency will then advise whether or not it falls within their remit and will advise whether or not a full proposal should be prepared. Changes that would improve the proposal's chances of being supported might also be suggested. One of the purposes of this two-stage approach is to allow the funding agencies to reduce the number of full proposals reviewed, so they can focus on the most promising ones. If an opportunity is given for submission of a letter of intent, applicants should make use of this before preparing a full proposal.

## 4.2. Funding committees

Decisions whether or not to fund applications are usually made or recommended by an advisory committee. In some funding schemes, applicants may be asked to attend for an interview, as part of the proposal review process. Members of these committees will have expertise in the general area of all the proposals they have to deliberate on. The identities of members of funding committees are usually made available, and it is a good strategy, especially if an interview is involved, for an applicant to read some of their recent work to try to guess some of the issues on which they are likely to focus in their questioning. The detailed discussions that funding committees have, in order to come to a decision on a specific application, are usually strictly confidential. The funding agency will usually convey an appropriate summary of the discussions, if relevant, to applicants. This is particularly useful if an application has been rejected, as a summary of the reasons for rejection may help the development of an improved proposal for the same or another funding agency. Most funding agencies regard it as highly inappropriate for applicants to have direct contact with members of funding committees regarding the application, and members are instructed specifically not to discuss applications outside committee meetings. Whenever a proposal is being reviewed where a member of the committee has a potential conflict of interest, they are usually asked to leave the room. Examples include where the individual or someone from their institution is involved in the proposal.

Funding agencies endeavour to support the best proposals where the research question, the timeliness of the study, the ability of the scientists involved, and the potential impact of the results all come together to make a compelling case for support of the proposal. In a proposal for an intervention trial, applicants should think carefully about how their study will stand out among potentially competing proposals. Whatever the area, the applicant needs to convey that the proposed study is important and timely and has achievable goals.

Most field trials are conducted in partnerships between research institutions and public health systems. For this reason, it is very important to have a clear definition of roles, responsibilities, and complementary expertise of the parties involved. How any ethical or legal issues related to potential consequences of the study will be handled should be carefully explained.

## 4.3. Competitive process

Obtaining grants is a highly competitive process. All agencies receive far more applications than they are able to fund, so a rejection does not necessarily mean that the proposal was weak. The decision on whether to resubmit a revised proposal to the same or another agency should take the feedback into account. Sometimes, but not always, the funding agency's officer administering the application may be willing to give advice on this.

## 5. Developing the proposal

When developing the proposal, it is wise to follow a systematic approach. In Box 8.1, a 10-step chronological, algorithmic approach is summarized that might be helpful for less experienced grant writers.

### 5.1. What is the problem, and why should it be studied?

The first step is to define clearly the *primary research question* to be addressed by the trial. Next, articulate why it is important and how the knowledge or evidence derived from the trial will contribute to addressing one or more health problems. Many proposals fail because too many questions are being asked and the proposal is unfocused.

### 5.2. What information is already available?

A good, but brief, *literature review* of what has already been done in the research area is an important element of any grant proposal. It demonstrates that the applicant has looked at the relevant publications to identify gaps and opportunities in the field on which the study is based. Wherever possible, past work should be summarized in the form of a systematic review, as discussed in Chapter 3. This stage should also include a review of any relevant registered trials that have not yet been completed.

### 5.3. What are the objectives of the research?

The title of a proposal is the first thing that the reader sees. After identifying the research question, produce a title that gives the reader a clear idea of what it is hoped to discover. Respect any word limits imposed by the funder.

The next step is to formulate the aims and specific objectives. These vary, according to the nature of the study. For a straightforward trial, for example, comparing the effects of two drugs, it may be relatively simple to state the aim. It may simply be to show whether drug A is superior to drug B in curing a specific disease in an individually randomized controlled trial.

In more complex studies, it may be necessary to articulate a general aim, followed by a list of specific objectives, some of which may include sub-objectives. Sometimes, several sequential steps may need to occur. In vaccine studies, for example, the immune status of the target population may need to be assessed first to select the target group for vaccination, and, before that, immunological assays may need to be developed, or tested and evaluated in the specific target population for the trial.

### 5.4. How will relevant information be collected and analysed?

The study design is a major component of a trial. Whether it should be placebo-controlled, double-blind, stratified, cluster randomized, etc. depends on many factors. State why a particular approach is necessary, and, if apparently superior designs have not been chosen, state why not. Many of these issues are discussed in Chapter 4.

The data to be collected and how they will be analysed must be described. If any of the data are to be from a sample of trial participants, the sampling technique needs to be explained and justified. Describe how the data will be processed and what statistical tests will be used in the analysis. Discuss any ethical, legal, and social issues that could arise from the specimen or data collection, storage, and dissemination. For example, it is important to describe informed consent processes for the trial population, what examinations will be performed on participants, and who will be responsible for their health care during the trial. Issues related to the taking, storage, and analysis of biological specimens should be addressed. If there are no previous published data to guide study design, will existing preliminary data or a pilot study be important? These issues are dealt with in detail in other chapters.

### 5.5. Community engagement plan

The proposal should include a description of how the community will be engaged in the planning and conduct of the trial (see Chapter 9). This should include a brief description of any formal structures, such as a Community Advisory Board (CAB), and other mechanisms that will be used to solicit the trial community's support and advice and to keep them fully informed of the trial's progress and results.

### 5.6. Who will do what and when?

The *work plan* is important to show in a logical way what aspects of the trial will be done and when. If a trial is 'high risk', this should be because the topic being studied is intellectually and conceptually challenging, not because it has been inadequately planned.

For nearly all trials, certain steps need to be conducted first, before others can proceed. A 'Gantt chart' is a helpful tool for project planning and presenting the proposed work plan, especially if there are complex dependencies among several components. Gantt charts are used to illustrate a project schedule, indicating in a graphical way start and end dates of specific components and activities to show how the individual tasks are sequenced.

It is important to identify specific milestones in the planning, conduct, and analysis of the trial and if strategic decisions will need to be made and when, such as whether the trial should continue or be stopped, given defined developments or outcomes.

Typical intervention trials involve large teams of people such as recruiters, interviewers, nurses, clinicians, laboratory technicians, public health officials, data management staff, statisticians, collaborators, and consultants. These have to be carefully managed, and their work budgeted for. In many cases, additional training may be needed. How the trial team will be managed and the work will be coordinated should be summarized in the proposal.

### **5.7. What are the risks?**

In any research undertaking, there is a chance that the objectives will not be achieved because of unexpected changes in circumstances. It is a good strategy to have contingency plans to cover areas where there are such potential risks. While it is impossible to anticipate all risks, list the known ones. Do not wait until reviewers point them out. It shows awareness and preparedness to alter plans without jeopardizing the main aims of the proposal. A good risk management plan would anticipate potential issues and corresponding solutions to prevent delays, increased cost, or poor quality to the study data. An example of a potential, and not uncommon, risk would be that the trial recruitment rate will be slower than anticipated. Potential ways of dealing with this could include close monitoring, so that remedial action can be taken early, using conservative recruitment estimates or planning recruitment at times in the year when the population is most accessible, for example. Contingency plans are particularly important in high-risk research. Identify the potential pitfalls, and describe how plans will change if they arise. For example, what is the alternative strategy if it proved impossible to conduct the trial in one of the trial populations?

### **5.8. What resources are needed?**

Some funding programmes invite proposals that must cost less than a specified amount, and it is necessary to design a study that fits within that budget limit. Whether or not there is a specified budget limit, much thought needs to be given to the budget. On the one hand, an inflated budget could render a proposal uncompetitive if equally strong proposals cost less. On the other hand, an under-budgeted trial may not be completed, and the results will be unpublishable. Be honest about what is needed. Discuss with the officer at the funding agency if guidance is required.

Funding agencies usually provide a list of costs that are eligible to be included in a grant application, i.e. costs that they are prepared to cover. It is important to study the conditions carefully. Salaries must be commensurate with qualifications, fairness, and compatible with local contexts. If equipment is being requested, maintenance costs may need to be factored in. In intervention trials, other costs associated with medical treatment and social care may have to be included. Some agencies do not fund institutional overheads or limit them to a maximum percentage of the total budget, so it will be necessary to check that these are acceptable to the applicant's institution in advance. Institutional contributions could be important to show their commitment to the trial.

Sometimes, it is possible to leverage donations of drugs or supplies from pharmaceutical companies—these can lower the overall costs and make a proposal more cost-effective to funders. If the specific proposal is linked to other projects, provide detail of what is already funded, and be clear about how much funding is being sought and how much will come from other sources. The key message is to cost the trial carefully, and justify all the costs requested.

### **5.9. How will the project be supervised and administered?**

The grant application should demonstrate, for the conduct and analysis of the trial, that the trial team either has all the necessary skills and experience or will have access to the appropriate expertise. This may include aspects of trial governance and monitoring of GCP and Good Clinical Laboratory Practice (GCLP) (see Chapters 16 and 17). It may be possible to delegate some of the trial procedures to specialist clinical research organizations (CROs). These units often have specialists in clinical trials to run certain aspects of a trial such as GCP or GCLP monitoring procedures.

Unless the trial is small, it is worth considering setting up a trial steering committee to guide and support the organization and monitoring of trial activities and guide its development, as the trial progresses. The steering committee should include members that represent a broad range of perspectives relevant to trial management. The steering committee also has the task of working with the DSMC to monitor progress and results without compromising the study design, especially in blinded studies (see Chapter 7).

### **5.10. How will results be disseminated?**

The results of intervention trials are generally expected to contribute to the formulation of health policies and practice. It is important to think about how the results of a trial might be used. Including policy makers and officials from the public health sector in the early planning and design stages of a trial, and keeping them informed during the conduct

of the trial, can lead to a faster adoption of trial results into policy and practice after the trial. Funding agencies like to see a quick impact for their funds, so specific provision for this in the application can be an advantage (see also Chapter 23).

Intervention trials, by their nature, often produce very large amounts of personal data and biological specimens. Specimen and data storage and access may present complicated ethical and legal issues. Who owns the specimens and data, who can see the personal data, how long the information and specimens should be kept, how the storage will be paid for, etc. are all pertinent questions. Funding agencies often require open access to data after the end of a trial, and the investigators may have to explain in their application how they will manage this requirement, taking into account confidentiality issues.

### **5.11. How will the application be presented to funding agencies?**

Most funding agencies have detailed instructions on the application process available on their Internet sites. Read the instructions carefully, and contact staff at the funding agency if anything is not absolutely clear.

Meeting deadlines is important. Sometimes, funding committees meet only once a year, and, if the deadline is missed, it may be a year before another submission can be made. Do not aim to submit just before the deadline—allow time, and submit ahead of the deadline. Sometimes, funding organizations need clarification if something is not clear in the application. Submitting early allows these issues to be sorted out, before the funding committee meets.

Do pay attention to details. Answer all the questions in the application form. For good presentation, make sure the proposal reads easily, for example, by minimizing the use of abbreviations and acronyms. Avoid technical jargon where unnecessary, and supply clear definitions of any technical terms that must be used. The proposal should be clear and succinct, free of contradiction or ‘leaps of faith’, and readily understood by scientists outside the immediate field of the investigator. Pay careful attention to its structure, ensuring it is logically ordered and argued. The aims and objectives of the proposal should be clearly defined at the start. Most space should be given to study design and methods. Use flow diagrams and figures where these will help the reader.

Allow time to go through the form several times. Make sure the final application is free of errors (spelling, typing errors, grammar, etc.), so as not to distract the reader. A carelessly put together application is often interpreted to indicate a careless investigator. It is valuable to have one or more colleagues, who have not been involved in writing the proposal, to review it before submission, as they will often pick up inconsistencies and errors that the investigator has missed simply through being too familiar with the proposal.

## **6. Responding to referees**

Many funding agencies allow applicants to respond to referees’ comments before the applications are considered by the funding committee. It is critical to make full use of the opportunity. Referees may have considerable experience in the field of the proposed research, and it is important to consider carefully their remarks and suggestions. Challenge comments that appear to be incorrect, preferably citing a reference. However, if suggestions are made that might improve the design of the study, consider carefully how the study might be modified to address the concerns, and include these in the response that will go to the funding committee. The length of the response allowed to referees’ comments is usually limited, so be precise and concise.

## **7. Funding decision**

Members of funding committees will usually have to read a large number of proposals in a relatively short period of time, and thus it is important that grant applications are written clearly and unambiguously to facilitate rapid understanding. Brevity, precision, and clarity therefore have great merit! The length of the grant application should be the minimum necessary to demonstrate the competence of the investigator and of the appropriateness and importance of the study proposed. It should never exceed the limits set by the funding agency. Reviewers will usually be annoyed, rather than impressed, with information, however erudite, that is not directly relevant to the research that is being proposed.

In reviewing a grant application, reviewers and committee members will be looking for the answers to some key questions, which are summarized in Box 8.2.

## **8. Common problems in grant applications**

The amount of detail to include on the trial design is a tricky one to get right. Some forms allow only a limited space, so care is required to provide the key details concisely but clearly articulated, so that reviewers can make an informed judgement. Standard methodologies can be simply referenced. A common fault is that applicants do not discuss obvious potential problems or limitations with their study design and just hope that they will not be picked up by reviewers. This strategy rarely works, and it is better to show awareness of the issues and explain how they will be addressed.

A list of common problems in grant applications is given in Box [8.3](#).

## 9. Roles and responsibilities

Expect a response from funding agencies in a timely manner. Most funding agencies will inform applicants of the date by which a decision will be made on an application. Remember that the reason for rejection may not be due to obvious flaws in the proposal but may just be that the application was not competitive, compared to others considered by the funding committee.

Remember that a successful application is only the start. Funders are interested in the progress of the project. They should be informed of any major findings, especially if there are going to be publications or if the results are controversial or groundbreaking. Funders may wish to publicize these, and they often have the resources to do so effectively.

Funding agency staff are usually prepared to offer advice on grant issues, and keeping them informed of important developments in a timely manner is advisable, for example, unavoidable delays to a study, changes to the study design, extension requests, etc. If delays are anticipated, it is much better to notify the agency early, so they are not wrong-footed but can work with you to mitigate the impact of these delays. For example, given sufficient notice, they may be able to revise the trial budget to allow money to be spent later than was originally agreed.

## 10. Further advice

There are numerous sources of general advice on how to write a successful research grant proposal such as a book by [Gitlin and Lyons, 2008](#). Some are even produced by specific funding agencies such as the Medical Research Council of South Africa (<http://www.mrc.ac.za/researchdevelopment/researchgrant.pdf>). Clearly, it is a smart move to read such advice if you are applying to an organization that provides it!

## Reference

Gitlin, L. N. and Lyons, K. J. 2008. *Successful grant writing : strategies for health and human service professionals*. London: Springer.

## Boxes

### Box 8.1 A 10-step guide to preparing a grant application

1. What is the problem, and why should it be studied?
  - Primary research question
  - Why is it important?
2. What information is already available?
  - Literature review
3. What are the objectives of the research?
  - Purpose of the trial
  - Specific objectives
4. How will the information be collected and analysed?
  - Study design
  - Data collection methods; sampling; data processing
  - Study size—what criteria and assumptions?
  - Data analysis methods
  - Ethical, legal, and social issues
5. Who will do what and when?
  - Work plan with a timetable
  - Human resources; collaborations; training
6. What are the risks?
  - Contingencies. Is there a ‘plan B’?
7. What resources are needed to carry out the research?
  - Budget
  - Justification
8. How will the project be supervised and administered?
  - Identification of advisors and planning for trial administration
  - Trial governance, including data and safety monitoring and trial steering committees, if relevant
9. How will results be disseminated?
  - Plan for utilization of research; identification of potential users of results
  - Data and sample archiving, access, and availability
10. How will the application be presented to funding agencies?
  - Submission forms; deadlines



- Attention to detail; presentation

### **Box 8.2 Key questions that reviewers and funding committee members will consider when reviewing a grant application**

1. What are the research questions that will be addressed by the proposed study?
2. Why is it important that this research be carried out? How will the study contribute, directly or indirectly, to the advancement of public health?
3. Are the applicants familiar with previous work in the area of the research, and does the study proposed build on and complement that work?
4. Have the applicants done preliminary or pilot studies that demonstrate the feasibility of the proposed research?
5. What is the research design, and how will it be implemented? Is the design appropriate?
6. Are the estimates of the impact of the intervention reasonable? Is the size of the study correct to detect an impact of the magnitude expected? Is the expected impact of the intervention of public health importance?
7. Is the time schedule for the work appropriate?
8. How much will the research cost? Are the costs justified?
9. Have the applicants considered the possible obstacles they might encounter in conducting the research and devised ways of overcoming these?
10. Have the applicants assembled the right team to do the research? What is their track record in research of this kind? Are their training and experience appropriate?

### **Box 8.3 Common problems with grant applications**

- ◆ Poorly formulated objectives.
- ◆ Too ambitious—trying to address too many questions in one study.
- ◆ Insufficient attention to previous literature on the research question.
- ◆ Poorly identified target population.
- ◆ Poor research design—inadequate attention to what specific research question is being addressed.
- ◆ Insufficient explanation of why it is important to answer this question and what impact it may have on public health practice.
- ◆ No data, preliminary results, or pilot studies to support the feasibility of the proposed approach.
- ◆ Inadequate description of the study design and procedures—derivation of sample size is often done poorly (consult a statistician!).
- ◆ Analysis methods not specified sufficiently in relation to the main objectives.
- ◆ Inadequate description as to who is doing what and when; lacking a detailed timetable for the research.
- ◆ Insufficient attention to quality and quality control.
- ◆ Inadequate allowance for data entry and analysis—often arrangements for analysis of data are not addressed at all in a proposal, other than that it will all go into a computer!

- ◆ Inadequately justified budget.
- ◆ Poorly structured; hard to follow the logic; inconsistencies.

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