Chapter 1 **Overview**

Many researchers in health sciences need to obtain funding in order to establish or continue with their work. This is a common activity in the non-commercial (academic or public) sector, such as universities and hospital research departments. The process of obtaining financial support is usually very competitive, particularly when there are limited resources. Funding bodies also need to ensure that their grants will be put to the best use, maximising the effect on clinical practice, public health, scientific knowledge or future research.

It can easily take 1–2 years (often more) from inception of a research proposal until the first subject is recruited to the study. This may sometimes feel daunting to researchers, especially those new to the field. However, as more people become involved and time is spent on developing the idea and study design, the likelihood of it being successfully funded should increase. If it has been thought through properly, major potential problems and design issues will have been considered and addressed in the application, rather than being raised for the first time by the funding committee or its external reviewers. It can be easy for experienced reviewers to distinguish a polished and cogent application that may have taken perhaps several months to develop and write, from one that has been written hastily in 3 weeks and only seen by one or two colleagues.

There is no such thing as a perfect grant application. The external reviewers and funding committee will usually have criticisms, and the applicants themselves often see ways of improving their application with hindsight. What largely matters is making the proposed project look important enough to be funded, that it is well designed, and that the financial costs are reasonable.

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1.1 Types of grants

Grants are used to investigate a multitude of study objectives:

- Examining risk factors for or causes of disease or early death.
- Examining the characteristics, attitudes, experiences or behaviour of defined groups of people.
- Evaluating methods for preventing, detecting or treating disease, or preventing early death.
- Laboratory experiments on biological samples, animals or simple organisms, in order to investigate the effects of a stimulus or exposure, identify associations, or as part of drug development.
- Correlating biological measurements with each other, or with patient outcomes, such as examining genetic, protein or other biomarkers associated with a disorder or early death.

The types of grants available to researchers include the following.

1.1.1 Project grants

These are the most common and are the type of grants with which researchers are familiar. The idea for a specific project is first thought of by one or two people in the field, who then establish a small group of colleagues to develop the idea further before applying for a grant. Alternatively, a project title can be first developed by a funding organisation, perhaps through an advisory committee, which has identified a need for a particular piece of research. The organisation advertises this (sometimes referred to as a *call for proposals*), and interested applicants then compete over who can address the research idea with the best study design and most acceptable resource requirements.

Project grants can cover any length of time, depending on the objectives, how common the disorder is and the number of expected participating centres. For example, a systematic review of a set of 10 published clinical trials, that involves obtaining raw data from each trial group, could take 12–18 months to complete, whereas a screening trial to identify people at a high risk of stomach cancer and to prevent it through adequate treatment could take over 10 years. An early phase clinical treatment trial of 50 patients could run for 2 years, compared with a late phase randomised trial of 500 patients that could take around 5 years.

1.1.2 Fellowships and doctoral (research) postgraduate degrees

These usually fund either a specific person who has formulated a research idea as part of his/her professional development, or a project proposal that has been advertised by a research department. Fellowships, which are competitive, are a sign of personal professional achievement if the grant application is successful.

They can be awarded to those who are already employed and the grant will allow the recipient to focus their research on a particular area for a fixed time period. Doctoral research degrees are common, particularly among people who are early in their career. The study objectives for these two types of grants are similar to those for project grants but are often smaller-scale studies, limited to laboratory experiments, or involving only a few centres for studies of humans, because funding is for a fixed length of time, for example 3–5 years.

1.1.3 Programme grants

Programme grants apply to a set of related projects in a particular field of research. These could fund a group of people with a common general research goal, or may support the formation of a core unit, either on its own or as part of a larger department, for example, establishing a clinical trials unit to design and conduct treatment trials in particular disorder. A programme grant can also be used to fund a set of new related studies to examine aspects of a disorder, for example, looking at different risk factors for heart disease, such as lifestyle characteristics, genetic and biological markers in blood or urine. These types of grants involve significant amounts of money and are associated with a duration of several years, for example 5 or 10 years, sometimes with the expectation that the grant will be renewed at the end of the period. Those who lead the units supported by these grants usually have prior experience with securing project grants and are established in their field of research.

Each of these three types of grants requires different levels of effort spent in the application process; the input is approximately in proportion to the funding requested. Programme grants are the most intensive to prepare because they are expensive, they will employ several people and last for many years. Project grants are perhaps the most competitive because they are usually open to any level of researcher, ie. those new to the field or already established. Grants for fellowships and research degrees tend to be offered by relatively few organisations, such as governmental research councils or charitable bodies, and are for short periods of time (up to about 3–5 years). These grants may be relatively easier to obtain, but elements of the grant application are similar to project grants.

1.2 Types of funding organisations

Several types of organisations provide funding for research projects:

- *Governmental bodies or research councils*
  - Department of Health/National Health Service (UK)
  - Medical Research Council (UK)
  - National Institutes of Health (USA) (see Yang 2005 for specific details about applying for NIH grants)

  - National Cancer Institute (USA)
  - Biotechnology and Biological Sciences Research Council (UK)
- *Regional or international funding organisations*
  - European Research Council
  - European Commission
  - Association for International Cancer Research
  - World Health Organization
- *Charities, disease-specific associations or foundations*
  - British Heart Foundation (UK)
  - Cancer Research UK (UK)
  - March of Dimes (USA)
  - Bill and Melinda Gates Foundation
  - Deutsche Forschungsgemeinschaft (DFG, German Research Foundation)
- *Local trustees within an organisation*: Some hospitals have a trustees' fund, which has accumulated from donations made by former or current employees, or by patients. Such funds are usually available to conduct relatively small-scale studies within that organisation (i.e. local or single centre studies), and not usually with national or international centres.
- *Commercial companies*: Some pharmaceutical companies and those that manufacture medical devices often provide funds to researchers in the non-commercial sector (e.g. a university), to conduct a clinical trial using one of their products. The drug or medical device may or may not already be licensed for use in humans, but it is almost always provided to the researchers without any cost. In some instances, the company also gives financial support to set up and conduct the trial in the form of a study-specific grant or an educational grant.
- *Private benefactors*: A researcher or research unit may have developed a professional relationship with a single, relatively wealthy individual who is willing to support them for a specific project. It is often the case that the benefactor (or his/her family member) has suffered from an illness related to the work of the researcher.

There is also a website called researchresearch.com that lists a wide range of funding organisations, including many of the smaller ones. The website is http://new.researchresearch.com.

Almost all grant applications will be considered by a funding committee, a group of experts with various backgrounds who are internal or external to the funding organisation. They will make the decision to fund a study or not.

Each funding organisation has its own process for grant applications. It is not the purpose of this book to cover specific agencies, nor to compare and contrast between them. However, the information required from prospective

researchers and many elements of the review process tend to be very similar, particularly for the larger well-known funding bodies. Details of the application process for a particular organisation should be available from their website, the application form or other documentation sent on request. Many regularly update their terms and conditions and requirements, so it is important to check these for each application as they may have changed since the last time the researcher submitted to the funding body. The organisation will usually have administrative staff available to provide advice on the application process by email or telephone.

Many application forms can be downloaded from the funding body's website (often in Microsoft Word), to be completed electronically and emailed or posted with the relevant signatures. Sometimes, there is an online submission form which is transferred directly to the funding body without the need for a hard copy (this is becoming increasingly common), though original signatures may still be expected to be posted.

1.3 Choosing an appropriate funding body

It will often be obvious which organisations are appropriate for funding a specific project, and large organisations sometimes have separate funding streams for different types of studies (such as laboratory experiments, observational studies or clinical trials). Colleagues with prior experience may recommend an appropriate funding body, or applicants could obtain information from websites or other documentation. When there are several potential funding organisations, the researcher needs to decide which might be the most appropriate after discussion with the Study Team (the group of people responsible for developing the study and who will usually be co-applicants; see Chapter 2). An application on the same topic should not be sent to more than one funding body at the same time with the expectation that this increases the chance of success. This is not usually allowed, and it avoids an unsatisfactory situation where two funding organisations approve the same study and applicants have to reject one.

Deciding which funding organisation to apply to may depend on the following factors:

- Whether there is a limit to the amount that can be requested, either each year or in total, or for single items of equipment.
- How wealthy the funding body is (small organisations are highly unlikely to fund large expensive studies).
- Whether or not the funding body will include institutional overheads (indirect costs) as part of the grant (see Section 6.2, page 82).
- Whether the application success rate for a funding body is low (usually because there are so many applications).

If the application is unsuccessful, it is always possible to submit a revised version elsewhere. However, the reviewers' comments should always be taken into account unless they are entirely inappropriate, because the next funding body may use one or more of the same reviewers. This may often be by chance, but is far more likely if the field of research is relatively narrow with a limited pool of appropriate experts.

1.4 Contents of the grant application

What is required from the applicants will usually be clear, either from the section headings in the application form itself or the guidelines from the funding organisation. Figure 1.1 provides an overview of the key features that are expected to be addressed in a typical grant application. Background, biological plausibility and justification, feasibility, and how the study results and conclusions will be used are covered in more detail in Chapter 3, while study design (which often forms most of the application) is discussed in Chapter 4. When there is no guidance from the funding body on the structure of the application (e.g. a commercial company or private benefactor), the main headings from Figure 1.1 could be used.

All projects should have a simple and concise title (one sentence). It is also worth creating an acronym for the study using letters from the title (sometimes the first letter from key words), or some word that encompasses the study aim, but check whether the same acronym is already in use for similar studies.

1.5 Including several studies in one application (project grants)

Most applications are associated with a single project, but there are occasions when several related projects are specified, though it is not meant to be a programme grant (see page 3). Sometimes, this approach is an efficient way to examine two or more objectives without having completely separate studies. For example, evaluating several treatments for a rare disorder as patients proceed through the clinical pathway from initial diagnosis to improvement, stable disease or progression, where different subsequent treatments are used according to level of recovery. Alternatively, there could be several related laboratory experiments, with specific but distinct stages.

Having too many sub-studies and objectives can make the application difficult to follow, or the overall project too complex. Occasionally, the funding committee may like parts of the project, but not others, and therefore need to decide whether to fund only these parts or decline the entire

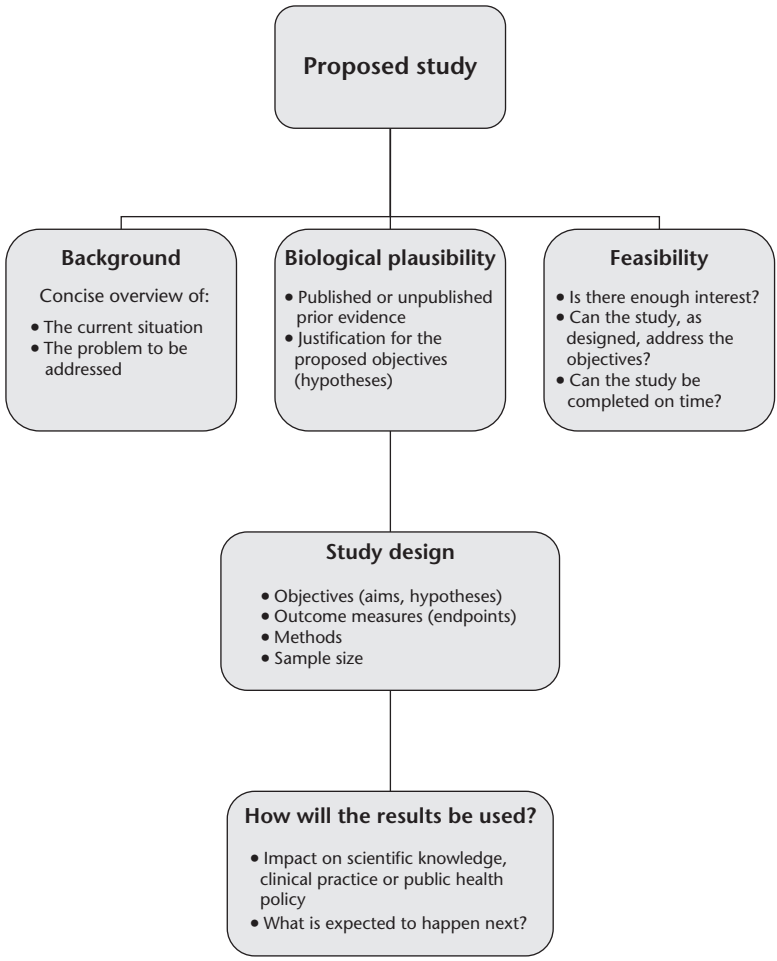

Figure 1.1 Key features of a typical grant application.

study. Applicants should, therefore, generally aim to avoid having too many sub-studies within a single application. If this approach is judged to be appropriate, applicants must provide a clear scientific justification, and show that there really is a central theme between the constituent studies. They will need to demonstrate that these are not different studies simply cobbled together. The applicants also need to ensure that one sub-study does not have an adverse impact on another, and that the results of any sub-study can be interpreted easily. A (simple) diagram showing how they all fit together would be helpful (see pages 38–39).

1.6 Translational research sub-studies

Many studies on humans, particularly case–control and cohort studies and clinical trials, will have clear objectives regarding a specific disorder or prevention of early death. However, it is becoming more common to collect biological samples as part of the main study, to be stored centrally in a laboratory for future, sometimes unspecified, analyses (i.e. the creation and maintenance of a *biobank*). This secondary analysis is sometimes referred to as a *translational research study*. The samples are usually blood, saliva or urine, but may also include tissue samples (e.g. cancerous tissue removed from affected patients). The analyses involve measuring biomarkers which could be chemical, biological (eg. genomic or proteomic markers) or radiological, that are to be correlated with clinical outcomes from the main study, such as response to a treatment, disease incidence, disease severity or mortality. Examples of this could be to examine the prognostic value of a biomarker (i.e. how well it correlates with a clinical outcome), its predictive value (i.e. whether the marker can be used to identify subgroups of individuals that are, for example, more likely to benefit from a certain treatment), or whether a biomarker can be used as a surrogate measure.

Adding a translational research sub-study could strengthen an application for the main study; the funding body may feel that they are getting more value for their money. Applicants may not need to describe in detail what the actual laboratory analyses will entail, because funding for the particular sub-study is sometimes applied for at a later date, or even from a different funding organisation. The application could briefly indicate the type of samples to be collected, when this will be undertaken, and whether there are any markers of current interest that would be measured. However, not all studies would benefit from having a translational study component, and indeed the collection and storage of biological samples could sometimes be a hindrance to the main study. The Study Team should decide together whether such a sub-study might be useful.

1.7 The application process

Figure 1.2 shows an overview of a typical grant application process (the funding committee evaluation is described in Chapter 7). Some funding bodies have an initial screening process for project grants, where an *outline application* is requested first and if there is sufficient interest, a subsequent *full application* is invited for the next committee meeting. Researchers should not underestimate the importance of an outline application. Although it is shorter and does not normally include details about the financial costs and collaborators, in reality the time and effort spent producing a well-written document may not be significantly less than that for a full application.

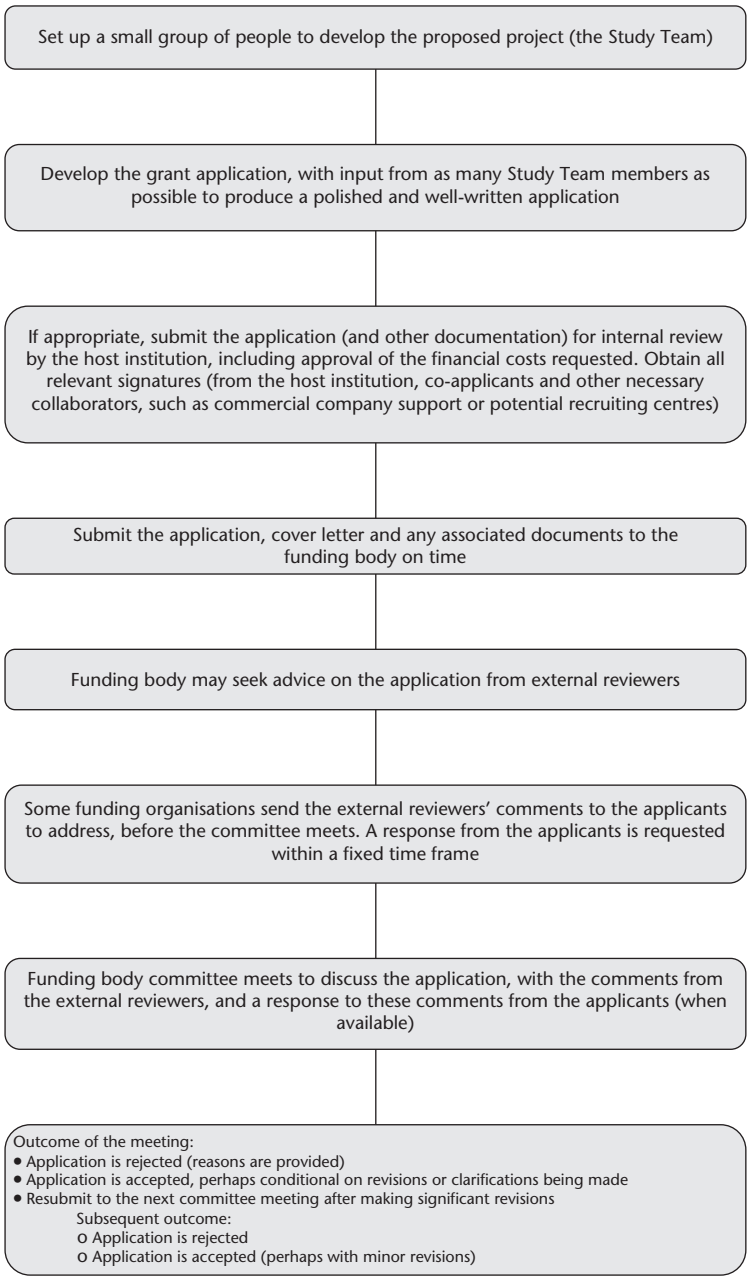

Figure 1.2 Overview of a typical grant application process.

Applicants occasionally rush the development of an outline application, and although they have reservations about parts of the text, they choose to submit anyway. There is little to be gained by this. It is likely that the review committee will have significant concerns and at best will request major revisions or clarifications, deferring consideration of the application to the next meeting. The applicants could have waited for the following meeting and spent more time on the application. A worse outcome is that the application is rejected outright, and there is no chance to revise the application and obtain funding.

Researchers should be aware that even before they submit their application to a funding body, it is often necessary for there to be an internal review by the host institution which will conduct the study, or act as the Sponsor in studies on humans (see Section 2.3, page 20). This review tends to focus on approval of the financial costs requested. It is usually signed by someone with financial authority, and the Head of Department.

Several other signatures may also be required, including those of all the co-applicants (see Section 2.1.1, page 19) and collaborators (see Section 5.4, page 76), and time needs to be allowed for this.

Almost all funding bodies have deadlines by which applications must be received.[1] Applicants should always submit their application on time. If there is likely to be a delay, the administrative staff at the funding body must be contacted beforehand, because in exceptional circumstances it might be possible to get an extension.

1.8 Estimating timelines and a planned work schedule

Many funding organisations request that the applicants specify the project *milestones* or *timescale* in the grant application. These are dates or periods during the course of the entire study over which certain tasks are expected to have been completed. Such schedules can only ever be approximate because unforeseen events, which often occur, can delay a project by several months. Estimated project milestones can nonetheless be useful to both the applicants and the funding body:

- They allow the applicants to see when certain tasks need to be completed, when different types of staff will be required and for how long, and when data are to be collected and analysed. This should all help with estimating the financial costs. It also gives applicants a rough schedule to work towards if successfully funded.

[1] Exceptions could be commercial companies who review project proposals frequently, for example every month.

- It allows the funding body to envisage a likely time frame for each part of the project, and to decide whether each section has an appropriate duration. If the grant is awarded, it is common for the funding body to request annual reports or updates from the researchers in order to determine whether the project is running on time, and if there are any major problems (see Section 8.1, page 115). These can be compared with the original milestones.

Box 1.1 shows typical parts of a project schedule. It does not have to be overly detailed, and need only indicate each major stage of the proposed study.

Box 1.1 Project milestones and possible associated activities

Milestone	Main activity (will depend on the type of study)	Length of time (examples of what could be specified)
Study set-up	• Develop and finalise the study protocol, and any other relevant documents such as the Participant Information Sheet and consent forms (human studies). • Develop, submit and obtain all study approvals (national, local/institutional, ethics, regulatory, etc.). • Set up recruiting sites. • Order laboratory equipment or other materials. • Obtain animals, and prepare and implement procedures for housing and maintaining them.	Year 1 (6 months)

Study conduct	• Clinical trial in humans
	  • Identify and recruit subjects.
	  • Intervention period.
	  • Follow-up period.
	• Observational studies of humans
	  • Identify and recruit subjects.
	  • Collect data (from questionnaires, interviews, hospital records, national databases, etc.).
	  • Follow-up period (cohort study).
		Years 1–4 (42 months); this could be divided further according to major activities.
		For example, in a clinical trial:
		Recruit subjects: 24 months
		Intervention: 6 months
		Follow-up: 12 months

(*Continued*)

Box 1.1 (Continued)

Milestone	Main activity (will depend on the type of study)	Length of time (examples of what could be specified)

	• Laboratory experiments
	  • Develop the methodology.
	  • Prepare the experiments, instal equipment.
	  • Conduct the experiment.	

Data analysis	• First analysis – discuss with the Study Team. • Second analysis – revised or additional analyses, discuss again with the Study Team. • Final analysis.	Year 5 (12 months)
Report	• First draft – review by Study Team. • Final draft – after incorporating comments from the Study Team. • Final report submitted to funding body (when required).	Year 6 (3 months)
Dissemination	• Submit for presentation at conference and for submission to journal.	Year 6

1.9 Intellectual property

Occasionally a proposed laboratory experiment or clinical trial could lead to a product or method that can be patented. In this situation, the grant applicants will need to ascertain who owns the intellectual property. It could, for example, be split between the host institution, the funding body and the research unit. Details, such as how much each party receives from the patent earnings, should be discussed before an application is made, and may be finalised after an application is successfully awarded. There may be a specific section in the application form on intellectual property, and administrative staff at the funding body can usually help with this aspect. If the study is funded and sponsored by a commercial company, the company will usually own any intellectual property. If a commercial company provides funds to conduct the study but an academic institution is the Sponsor, an agreement would have to be made between these two organisations over the distribution of the patent, and this would be specified in a formal contract.

1.10 Text, grammar and format

It should be obvious that the text in a grant application should be easy to read, clear and where possible free from (or have limited) overly technical jargon. Also, abbreviations should be kept to a minimum, except those that are well-known and in common use in the field. Non-scientists will often be a member of the review committee for applications for studies on humans, and it is sometimes frustrating for them to try to understand exactly what the proposed study entails. Even technical laboratory experiments, which tend to be reviewed by like-minded experts, can benefit from simpler language in many sections of the application, where possible. Simplifying the text can indicate that the applicants know their subject matter well, because they can communicate to a high standard. This can improve the chance of success. Funding committees and external reviewers who struggle to understand an application will often cite this as a specific criticism. An application with many grammatical and spelling mistakes will appear unprofessional, and may be viewed negatively. The more people who have read and commented on the application prior to submission, the more likely that the application will read well.

The application form, or funding body guidelines, will specify the font size and other formatting characteristics, such as the preferred referencing system. The whole application should be examined before it is submitted to ensure, for example, that all the text has the same font size and that headings and numbered sections follow logically.

Applicants should aim to keep within the word or page limit for each section (if specified), but nevertheless avoid having an overly long application. The funding committee and external reviewers will have difficulty in reading through many pages of dense text. If the application is easy to read, the reviewers will understand and interpret the proposed project more readily, and this can indicate that the applicants have a good grasp of their study. It is best to have short paragraphs, avoid long sentences, and use subheadings in each section when appropriate, because this can greatly improve the structure of the application. For example, within a main section associated with the justification for a clinical trial of a new drug, subheadings for 'Biological mechanism', 'Prior evidence on efficacy' and 'Prior evidence on safety' could be created. Applicants should also identify if any repetitive statements are made within or between sections, and edit or remove them.

Some grant applications are improved by including tables or diagrams. These should be of good quality (i.e. high resolutions), and may often convey information in a clearer and more succinct way than using extensive text. Applicants need to ensure that the tables or diagrams are relevant to

the proposal, are labelled properly, have clear legends and symbols, and if taken from published sources, are correctly referenced. Overly complex or detailed tables and diagrams are difficult to interpret and can hinder rather than aid the interpretation of the application. Colour illustrations might seem appealing, and in some cases are necessary, but applicants should bear in mind that the application will probably be printed in black and white. Some funding bodies send the application electronically to the committee and reviewers. Although this saves printing costs and items in colour can be seen on a computer screen, many reviewers still prefer to read through a hard copy and will therefore print them off anyway.

Summary points

- Know the application process and the timelines, including any prior internal approvals required by the host institution.
- Allow sufficient time to develop the application with several colleagues, so that the ideas can be considered carefully, major issues are identified and addressed, and the text looks well written.
- Do not have dense sections of text; use short paragraphs and short sentences, perhaps with section subheadings.
- Use simple tables and diagrams to summarise information or describe parts of the methods.
- Aim to have several versions of the application (at least five), with significant improvements between each revision.
- If the submission deadline is close, but the application has not been thoroughly evaluated or is not well written, consider waiting for the next deadline (if possible).
- If the text does not read well, or applicants themselves have concerns, do not submit and take a chance to see what happens, because this can look unprofessional and affect future applications; wait for the next deadline.
- Make sure that the current version of the application form from the funding organisation is used.
- Carefully read the instructions for submission from the funding body.
- Do not send the same application to more than one funding organisation at the same time.
- Do not combine several unrelated projects in the same application (unless specifically allowed).
- Contact administrative staff at the funding body over any general queries.
- Do not submit the application after the deadline has passed (even if by only a day), unless you have explicit permission to do so by the funding body.