7.3 How to write a successful grant application for a research study

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7.3.1 Learning objectives

To understand the general components of a grant proposal, by outlining some key principles and tips for success, including:

1. Components typically required in a grant proposal.
2. Process by which granting decisions are made.
3. Tips to increase the chances of success and avoid common mistakes.

7.3.2 Introduction

A grant is a monetary award given from a funding body; a grant application contains the details of a proposed project, and is used by the funding body to decide whether to award a grant. Grants are an important financial resource to support research, to enable training and to facilitate sharing of the latest evidence from research.

This chapter provides an overview of the steps for preparing and designing a grant application suitable for submission to a funding agency, with particular emphasis on research projects relevant to health emergency and disaster risk management (Health EDRM). The chapter discusses the components of a grant proposal, how to choose the most appropriate funding body to apply to, how the grant application will be processed and tips to increase the chances of success.

Before applying for a grant, some of the first steps to take are to:

- Recognize a service need or research gap, or have an idea.
- Identify the outcomes that the research study might have and work backwards to design a plan for how to achieve these.
- Generate several ideas and narrow these down, based on what is appropriate and feasible.
- Look for funding opportunities to identify grants that would be suitable for the project and for which the project would be eligible.

- Secure partners to establish a working team, which might include members of the public from the populations that will participate in the research.
- Prepare the grant proposal, and address the items as listed.

There are many guides to help new researchers to prepare a grant application, some of which are signposted in the Further Reading section at the end of this chapter.

7.3.3 Grant Proposal

A grant application usually includes a research proposal, which summarizes how the proposed project will be planned, implemented, monitored and reported. The exact content of the proposal will vary depending on the type of grant and the funder's requirements. For example, a grant application might seek funding for academic research on a health emergency or a scholarship to support postgraduate learning, or might be smaller in nature – in order to support attendance at a training event or conference, for example. Sometimes, funds might be sought as seed money for a pilot study or as matching funds to be combined with other sources of funding. Although there is wide variation in proposal formats, Table 7.3.1 shows the components commonly found in grant applications for research studies.

Table 7.3.1 Common components of grant proposals for research

Item	Content
Title	Short project title.
Summary	Summary of the proposed study (usually 200 to 400 words).
Introduction and Background	Background and rationale for the study to show its importance. Description of the current problem and the new study's research questions. Review of existing body of knowledge. Details of the intended participants.
Methods	Justification for the choice of methods. Description of the methods, including: - study design; - sample size and sampling method; - implementation procedures (for recruitment and follow-up for example); - plan for data collection, analysis and interpretation.
Discussion	Plan for reporting and dissemination of findings. Expected outcomes and impact of the study.
Limitations	Limitations of the methods, and risks to the project. Mitigation plans to overcome any difficulties.

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Item	Content
Timeline	Time needed for each part of the project (perhaps as a Gantt chart).
Budget	Budget and justification for separate items. Details of any other funding for the study.
Ethics consideration	Ethical issues and process for obtaining ethics approval.
Research team	Information about each member of the research team.

A key aim for a grant proposal should be to present an exciting idea for a research study, that has been transformed into achievable actions and that will provide evidence to fill an important gap in knowledge. The gap can relate to uncertainties in the topic area (for example, to measure a health problem in an emergency and its impact on the population, or to identify the effects of an intervention) or knowledge mobilization (for example, moving available knowledge from research into practice). The existence and importance of the gap might be supported, for example, by a systematic or scoping review of existing research (Chapters 2.6 and 3.6), statements from experts in the field, data from previous research, examples of similar research, a prioritization exercise (Chapter 2.7), or community-based research and asset mapping (Chapter 3.1). In the proposal, it is necessary to demonstrate the applicants' knowledge of current developments in the field and the ability of the research team to deliver the study and uphold the standard of good quality scientific evidence.

Application requirements vary considerably across funding agencies. For example, some funding bodies encourage collaboration between different organizations, others prefer a simple but clear plan without the complications of project dependencies. For research studies with multiple partners and locations, the grant proposal will require clear identification of the qualifications, experience and roles of each research team member. It will also need a justification for their involvement and the costs of doing so.

7.3.4 Grant writing

Grant proposals should be written in a way that will allow peer reviewers from unrelated disciplines to understand the problem to be researched, the methods to be used and the importance of the project. Some of the people that the funder will ask to assess the application may be non-experts, so it is important for the proposal to be understandable to a range of audiences and to avoid jargon. It is helpful to use short and clear examples of what is being studied and why, to provide the assessors with a visual picture of the overall plan.

It is common for funders to ask for a cover letter to accompany the grant proposal and this is an additional way to stress the importance of the study. It is an opportunity to state the need for the project clearly and explicitly, and to show how the proposal meets the eligibility criteria for the grant. The request should clearly state and quantify on what and how the grant will be used, and the benefits to both the researcher and the funder of it being awarded. It is best to use the active voice to emphasize the plan of action. In

addition, if there is sufficient space and it is acceptable to include diagrams and infographics, these can be used to illustrate complex concepts. As with the final report of the study (Chapter 7.7), it is important to check the application carefully for spelling and grammar before it is submitted, and it may be useful to employ an editor or ask a friend to proofread it.

Case study 7.3.1
Example of a research grant on Health EDRM *(1)*

Project title: Optimizing a community-based model for case identification, monitoring, and prevention of hypertension and diabetes among Syrian refugees in the Hashemite Kingdom of Jordan

Funder: Elrha's Research for Health in Humanitarian Crises (R2HC) Programme. R2HC is funded by the United Kingdom's Department for International Development (DFID), Wellcome, and the United Kingdom's National Institute for Health Research (NIHR).

Funder requirements	Project characteristics that match the requirement
Scope: research that will strengthen evidence-based practice around a public health intervention in humanitarian crises.	Research to investigate and improve a community health worker based model for noncommunicable disease care in a humanitarian emergency among Syrian refugees in Jordan.
Impact: demonstrate the potential scale and impact of the proposed research.	The outcomes of this project will be replicable in other contexts (for example, non-refugee emergencies) and will provide a strong case for addressing continuity of care for urban refugees through community health workers.
Methodology: robust innovative methodologies of a standard publishable in peer-reviewed academic journals.	Qualitative and quantitative methods (population-based survey) will be used, including a cost-efficiency analysis. Citing previous work of the research team in the topic area will highlight their experience with the chosen methods.
Partnerships: applicants must have a research team including both a research institution and an operational humanitarian organization	University of Southern California, International Rescue Committee, Jordanian University of Science and Technology, and Brigham and Women's Hospital.
Duration: 36 months.	September 2018 to August 2021.

7.3.5 Funder requirements and suitability

The funder for a research study might be a (federal or state) government agency, a public or private foundation, or a corporation. The funder will have requirements as to the applicant's legal authority to apply for a grant,

whether the applicant is an organization or individual. For example, there are grants specifically aimed at funding partnerships between voluntary and governmental organizations, and grants targeted at people holding an academic position or belonging to certain resident groups. It may be helpful to look at previous grants made by the funder to explore the type of research that they are likely to fund and the content of successful applications.

Grant opportunities might be identified by searching online sources, through the research offices of academic institutions, or by identifying potential funding agencies. Other resources include checking the grant histories of individuals who have similar research interests or asking colleagues with a similar level of expertise. Subscription-based websites, such as Foundation Directory Online and GrantWatch have extensive information in their donor databases.

The National Institutes of Health in the USA, Canadian Institutes of Health Research and the United Kingdom's Wellcome Trust are the top three funding agencies, with the highest number of grants among 12 major funders for health research *(2)*. However, a limitation of all three is that they mainly support academic research at universities in their own countries *(2)*.

The largest source of research and development funding for health is from the business sector, followed by the public sector, and then other sources (including private NGOs) *(3)*. The private sector can be a good source for funding and, although many of these grants support clinical trials on diseases such as cancer, it is worth exploring any that would be a good fit for a project in Health EDRM. Table 7.3.2 lists some websites that contain information for private foundations and corporations that award grants for health research.

Table 7.3.2. Websites for identifying research funders

Funder or organization	Website
Foundation Directory Online	fconline.foundationcenter.org
GrantWatch "Disaster Relief Grants"	www.grantwatch.com/cat/48/disaster-relief-grants.html
WHO Centre for Health Development	extranet.who.int/kobe_centre/en/calls-tors

7.3.6 Allocation of grant funding in different phases of the disaster cycle

There are four phases of the disaster cycle: prevention, preparedness, response and recovery. Research has shown that investing in disaster risk reduction (DRR) measures before a disaster is several times more cost effective than funding the response to disaster *(4–5)*; however, prevention and preparedness are a low priority for attracting funding in comparison to the response and recovery phases. Donors are quick and generous in giving immediately after a major disaster, but donations trail off within a short period. Therefore, finding a way to place prevention and preparedness within response and recovery may increase the chances of

success for a grant proposal, as well as providing the stability required for widespread implementation in Health EDRM.

International aid for disasters from 1991 to 2010 was spent mainly on emergency response (US $69.9 billion, 65.5%) or reconstruction and rehabilitation (US $23.3 billion, 21.8%). A smaller proportion of the funding went to DRR (US $13.5 billion, 12.7%) *(6)*. In 2016, foundations and public charities allocated their global disaster-related funding as follows: 42% for response and relief efforts, 17% for reconstruction and recovery, 8% for resilience and 5% for disaster preparedness *(7)*. Furthermore, more than two thirds of private giving stops within two months of a sudden disaster, and all giving peaks by five or six months *(8)*.

7.3.7 Developing a grant budget

A vital part of planning the research study that is also vital for the grant application is identifying, well ahead of time, where to get assistance and who is needed beyond the immediate team. This will have an impact on the project's budget; an advisor or programme officer may help to determine what expenses will be regarded as reasonable. For example, funders are unlikely to pay for new computers for all members of the research team or for holding research meetings in expensive locations. What is important is that the funding will be sufficient to complete the research, which means that it is critical to request the correct amount of funding.

An effective proposal budget is an accurate assessment of all expenses, provides justification for each item of spending and explains how the costs were arrived at. The timeline for the project needs to be taken into account, as well as the items for which funding will be requested. It is also important to consider the length of time that might be needed by the host organization for the grant in order to approve the proposed budget (if necessary), as well as how to respond if the costs are challenged.

Typically, a research study's budget will include direct costs and indirect costs. Direct costs are project personnel salaries and employee benefits, equipment, supplies, services and travel. Indirect costs are those incurred in the project which cannot be identified specifically, and usually include the money needed for the services provided by the host organization (for example, administrative, procurement, accounting and finance, security, library and so on). These costs are often referred to as overheads, overhead costs, or facilities and administrative costs. They are sometimes calculated as a predetermined proportion of the project's direct costs.

Expenses for personnel will include some or all of the salary or wage for each person on the project (depending on what proportion of their time they will devote to it), as well as employee benefits such as pension expenses, social security contributions, statutory and voluntary medical insurance contributions.

7.3.8 Grant review process

Funders wish to choose well-organized and compelling ideas from among the many proposals submitted to them. They will select applicants who they feel are capable of successfully implementing the proposed project, in accordance with the requirements and eligibility criteria for their funds.

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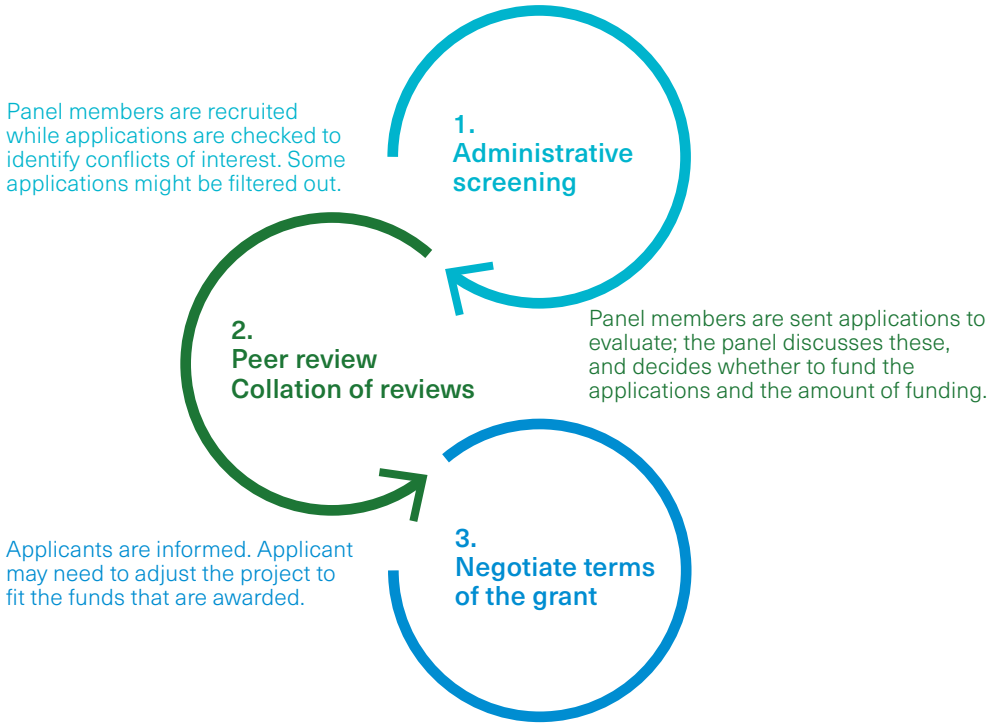
The funder's guidelines for the application are usually accompanied by information on the objectives of their grants and criteria for evaluation. To increase the chances of success, it is important that the applicant strictly follows the proper format for the application and submits all the required materials.

After a grant application is received, the funder's administrative staff will usually check its completeness and eligibility for the grant before assigning it to peer reviewers, a specific panel or both. Most decisions on research funding are made by a panel of experts who assess the applications and might interview the applicants. The panel assesses the proposal against a set of criteria. A summary of the assessment and any peer review is usually sent to the applicants, sometimes with an opportunity for them to respond before the funding decision is made. The funder would then either offer the grant to the applicant, decline to do so or, occasionally, offer a smaller amount of funding than that requested. Negotiation with the funder may then be possible, as well as adjustments to the project goals, objectives and timelines to match the reduced funding. The whole process from submission of an application to the decision usually takes at least three to six months and can sometimes take more than a year (Figure 7.3.1).

Figure 7.3.1 Grant review process



7.3.9 Managing a grant

Obtaining a funded grant is an achievement and indicates the proposal's appeal to the funder. Implementing a new grant requires good project management and administration. If the grant is for an organization, the relevant department would set up a grant budget account and oversee logistics of monitoring expenditures. Collaboration may also be needed with the human resources department to hire new personnel. A key next step after the grant is awarded may be an application for ethics approval (Chapter 7.4) and it is important to do this as early as possible, because the process can take several months and the study will not be able to start without the necessary level of approval.

7.3.10 Conclusions

There are many resources available that provide advice on preparing grant applications – this chapter outlines how to get started. To be successful, a grant proposal must be persuasive, realistic and written in a way that will appeal to the funder. In the end, success is likely to be a mixture of skill and luck; and the following tips may help:

- Address the objectives of the grant first, and explain how the objectives of the project will complement the grant.
- Identify service and knowledge gaps, and explain how the research will fill this gap.
- Show preliminary data related to the funding call, including records from previous work, feasibility research or pilot projects to demonstrate the proficiency of the research team.
- Show the track record of the research team, including listing related work and bring necessary expertise into the team where this is lacking.
- Choose and be prepared to train responsive collaborators who will complement the initial team and who will help to complete the project, problem-solve, be flexible and maintain a positive transparent outlook.
- Quantify the potential impact of the research.
- Be clear and easy to understand, illustrate with figures, infographics and photographs.
- Support the application with scientific evidence and relevant references.

7.3

7.3.11 Key messages

- **A grant proposal summarizes the idea and components of a research study.**
- **Connections with reliable people with similar research interests and exploration of funding sources in the applicant's area of expertise will help to ensure that there is a good fit between the application and the funder.**
- **The eligibility criteria for grants and the requirements of funders vary widely, making it important to check grant criteria carefully.**
- **Previous grants made by the funder may provide a good guide to the type of research they are likely to fund and the content of successful applications.**

7.3.12 Further reading

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7.3.13 References

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7.4 Getting ethical approval for your research

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7.4.1 Learning objectives

To understand the following in relation to applying for ethical approval for a research study in health emergency disaster risk management (Health EDRM), with a focus on WHO guidance:

1. The general processes involved in ethical approval of research projects.
2. The types of document that are usually needed for an ethics application.

7.4.2 Introduction

Research is an essential component in public health – it is the gateway to evidence on the effects of interventions, disease trends, health system structures and processes. In the context of Health EDRM, research is especially important for investigating the effectiveness of emergency prevention, preparedness, response and recovery, and providing an evidence base for decision making. Research that involves human subjects, regardless of the form of sample/record taken and study design, require ethics approval in order to ensure that the people who participate in research are treated ethically, not taken advantage of, and that the research procedure is carried out to high ethical standards; this is discussed in depth in Chapter 3.4, with particular issues for at-risk groups described in Chapter 2.5. Researchers have a duty to promote and ensure respect for all human subjects and protect their health and rights *(1)*. Specific morals that need to be upheld include respect for persons, non-maleficence, beneficence, justice and utility. According to WHO *(2),* all research involving human beings should be reviewed by an ethics committee. Studies that involve human participants but are potentially exempt for ethics approval, e.g. using public available data only, should also be reviewed by ethic committees to confirm exemption. Ethics approval should be obtained before the study begins from a recognized ethics committee – this chapter introduces the procedure and basic components required for obtaining ethics approval.

7.4.3 Where to request and obtain ethics approval

A research ethics committee (REC) has the responsibility to ensure the ethical safety and scientific merit of the research. It has the authority to reject, approve or cease the research and to require modification to the research protocol. The main responsibility of the REC is to protect the safety of potential research subjects and to evaluate the risks and benefits brought to subjects and the community. In general, RECs evaluate research proposals with reference to established ethical documents *(3-4)*. Each REC may have its own standard. For example, the WHO ethics committee *(5)* is guided by the World Medical Association Declaration of Helsinki *(1)* and the International Ethical Guidelines for Biomedical Research Involving Human Subjects *(6)* . Hence, researchers should check with the REC they intend to approach (in their academic institution, region or country, for example) to identify the documents that will need to be submitted with their application.

RECs are usually based in regional or national public facilities or individual academic institutions. They usually consist of scientific members (with related research expertise) and non-scientific members (with diverse backgrounds) in order to provide for a comprehensive and quality ethical evaluation.

Individual institutions may have their own committees as an internal regulatory process, such as an institutional review board (IRB) or University Human Research Ethics Committee (UHREC). These have the advantage of being able to evaluate the research protocol with local and familiar perspectives and to monitor the study more closely. For example, the community ethics committee of the Center for Bioethics of the Harvard Medical School *(7)* has members from the Greater Boston area, which makes the ethics review a better fit with the local culture and needs. However, financial interests within the studies may present challenges for a local REC such as this to refuse an application or to request significant changes to the research protocol. For that reason, regional or national committees might provide a stronger legitimacy and consistency when reviewing research conducted by the public and research community. For example, the National Health Service (NHS) in the United Kingdom has a Health Research Authority, which is responsible for the management and conduct of national-level research, including the REC process *(8)*.

7.4.4 Research approval for studies that will take place beyond local regions

For studies that will be conducted outside the researchers' local region, the researchers should ensure that the proposed procedure is locally acceptable. The study design should take local culture and tradition into account, and there should ideally be input from local researchers *(9)*. Furthermore, researchers may be required to obtain approval from the relevant foreign authorities, as well as from their host institution. This may require a request to a REC close to the target community, to ensure the evaluation of the research procedures for cultural and legal appropriateness. As Wright, Parker and the Nuffield Council on Bioethics Working Group *(9)* argue, the decision-making of funders, research institutions, RECs and many others should be centred on the priorities and

needs of the local community they try to support.

When applying to the researcher's host institution, the application should indicate that the study will be an international study and that approval from a local REC will be obtained after approval by the host institution. Likewise, the application to a foreign institution should indicate that approval has been obtained from the host institution. When preparing these applications, it is important to remember that the different RECs may follow different processes and require different documents.

7.4.5 What if no REC is available in the affected area?

If no REC is available in the affected region/country during a health emergency or disaster, alternative actions may be needed to obtain ethics approval *(10-11)*. There is no consensus guideline for this type of situation, but some possible courses of action and their limitations are shown in Table 7.4.1.

Table 7.4.1 Obtaining ethics approval if a local REC is not available: Some possible actions and their limitations

Action	Limitation
Ask the relevant local representatives or authorities (such as village elder or community leader) for agreement and obtain ethics approval from researchers' local region.	Approval might be biased to one or a small number of local authorities.
Ask the relevant local representatives or authorities (for example, village elder or hospital director) to organize a review committee.	It takes time to organize a committee and the members might not have the necessary experience for review and decision.
Obtain ethics approval from an international organization (such as WHO).	Approval might not have considered local context.
Obtain approval from an established special review board.	It takes time to organize the committee and must be organized by a trusted organization.

7.4.6 Types of ethics review

Different levels of ethical review may be required depending on the invasiveness of the procedure, urgency and the design of the research. Furthermore, review levels vary across different institutions. The researcher should check the requirements of the target institutions before submitting an application. WHO uses five common types of ethics review for proposals *(5)*, which are outlined below.

Full committee review of proposals

Research proposals that present more than minimal risk to human subjects are reviewed by two REC members who present the proposal to the full committee, which then has a general discussion before reaching a consensus decision (see Section 7.4.7). Researchers responsible for the proposal under review are subsequently invited to respond to queries

raised and to provide clarifications or justifications.

Expedited review of proposals
The proposal is circulated for expedited review when the research procedures present no more than a risk of minimal harm to the research participants or communities. In this case, the proposal is sent to two REC members who are required to provide their feedback to the secretariat within 15 working days. The proposal is then either approved or returned to the researcher for further action.

Exemption from REC review
Proposals are exempted from review if they represent less than minimum risks to participants.

Accelerated review
In a public health emergency, such as the investigation of a disease outbreak or a disaster relief operation, an application may be submitted for accelerated review. This is discussed further below.

Continuing review
Since ethics approvals are valid for a limited time period, the REC reviews the progress of the study at periodic intervals. In order to renew the approval, the researchers should submit the necessary documentation to the REC before their approval expires.

7.4.7 Definition of minimal risk

In some decisions around ethics approval, the REC may consider the concept of "minimal risk". There is no global consensus on minimal risk, but similar definitions are used by many organizations and countries. For instance, Australia, Canada, South Africa, the USA, and the Council for International Organizations (CIOMS) have a standard for minimal risk which revolves around comparisons and interpretations of 'everyday risks', 'routine examinations' and 'best interest' of the studied population. These standards need to be adjusted for vulnerable research participants such as prisoners, incapacitated adults and children *(12)*. Researchers should check the minimal risk definition of the REC they are applying to before submitting their application for ethics approval.

7.4.8 The need for accelerated review: Limitations of the non-emergency ethics review process during emergencies

Although most of the ethical issues in emergency-related research are not unique to emergencies, in an emergency the perceptions of potential harm, benefit, and trust (including the patient-provider relationship) differ, and this should be considered in the ethics review, as discussed in Chapter 3.4 *(13)*. Furthermore, research during an ongoing emergency or disaster is likely to require a faster approval decision. Accelerated reviews are designated for this purpose, but some existing ethics review system cannot accommodate these. In considering this, Kayano and colleagues *(14)* emphasized the importance of ethics review systems evolving constantly; this is discussed in Case Study 7.4.1.

7.4

Case Study 7.4.1
The value of an accelerated ethics review process

Many existing ethics review systems are established to operate in non-emergency situations. However, for emergency research, the complexity of the emergency setting may make it difficult to address practical ethical issues. In such contexts, ethics governance may need to consider non-ideal ethical and methodological approaches rather than insisting on the ideal situation in humanitarian research *(15)*. Decision making will require striking a balance between speed and ethics, with the addition of the voice of the affected communities.

For example, during the Ebola outbreak in 2014-2016, WHO *(16)* was responsible for reviewing and discussing ethics for various interventional and observational studies to control the outbreak. The WHO REC established a subcommittee to conduct accelerated reviews to facilitate this process. This was the first time that the accelerated review was put into practice. The subcommittee reviewed 24 new and 22 amended applications, with an average reviewing time of 6 working days.

7.4.9 The research protocol: what to include when preparing an ethics application

This section lists the documents commonly required as part of an ethics application. However, researchers should always check and understand the specific requirements of the REC they are applying to before submitting their application.

Research Protocol
This is the core document of the application. It describes why the study is needed and how it will be conducted. The WHO recommended format for a research protocol is that it should have the following components *(17):*

- **Project summary:** This summary should include the rationale, objectives, methods, participants, time frame and expected outcomes.
- **General information:** This should include the protocol title (identifying number and date), investigators, sponsors and the locations and institutions where the research will be done.
- **Rationale and background information:** This should describe current knowledge about the research topic and intervention, and the need for the research to be conducted in a disaster, rather than a non-disaster, setting. The proposal should provide basic information about the target population, and the potential benefits and harms of the intervention to them. It should also explain the expected benefits from the research and how these outweigh any potential harms of the study.
- **Study goal and objective:** This should include the intended outcomes and aims for the research, and should be considered alongside the research question (Chapter 3.5).
- **Study design:** This should include the type of study (as discussed in Section 4 of this book) *(18)*, target population, the recruitment procedure, research or diagnostic tools and duration of the study. Information on the study's inclusion and exclusion criteria and any criteria for withdrawal should also be mentioned.

- **Methodology:** This should provide detailed information about the research procedure. This would include information on how the following will be conducted: interventions, measurements, observations, laboratory investigations, and procedures. How participant confidentiality will be ensured should also be included. Standardized and clearly defined procedures will be required for any sites where special protocols are needed. For studies in disaster settings, providing participants with sufficient information about the study and the freedom for participants to choose whether or not to participate are especially important (see Chapter 3.4) and should be clearly stated in the protocol. If the study involves an intervention, the standardized and documented procedure (for example, the frequency of study visit, intervention procedure) should be clearly described and evidence supporting the interventions should be provided (see Chapter 3.3). The procedure for receiving questions and feedback from participants should be clearly defined. If the study is a randomized trial, additional information on randomization, blinding or masking and any stopping criteria for ending the research prematurely will be needed (Chapter 4.1).
- **Safety consideration:** This should describe how safety of participants will be ensured and how adverse events will be recorded, reported and managed.
- **Follow-up:** This should describe what follow-up activities will be provided to the research participants and the duration of this follow-up – for example, follow-up activities relating to data collection or monitoring of adverse events.
- **Data-management and statistical analysis:** This should describe how the data collected will be processed, stored and analysed. Physical and electronic data may have different management protocols and information should be provided about which personnel will have access to the data, and how the confidentiality of participants will be protected.
- **Quality assurance:** This should describe the quality control and quality assurance system for the research, e.g. clincal monitors and data management.
- **Expected outcome of the study:** This should discuss how the study results might contribute to the advancement of knowledge, how the findings will be made available, and how it may impact on the health services, systems and policies.
- **Dissemination of results and publication policy:** The dissemination process for the findings of a study should include information on the method, policy and responsible personnel, target audience (relevant policy makers, scientific media, the community and participants, for example).
- **Duration:** A detailed timeline of the project should be provided, ideally in months and beginning from the point that ethics approval is received.
- **Anticipated challenges:** This should include the foreseeable problems and possible solutions for the study.

- **Project management:** This should describe the roles and responsibilities of each member of the research team.
- **Ethics:** This should describe the ethical consideration. Even in the context of emergency and disaster situations, ethics issues such as time to reflect on to take part in the study or not and the right to withdraw, should be respected. Any procedures that might raise specific ethical issues should be discussed. This section should also describe how informed consent will be taken during recruitment and the relevant documents should probably be included in the application, as discussed below.
- **Conflict of interest:** The researchers should declare any interests that any of them have which are related to the study or its results and might be regarded as a conflict. WHO provides guidance for this online in Guidelines for Declaration of Interests *(19)*.
- **Budget and other financial support:** Some RECs require details on the study's budget and funding source. Researchers should check whether the REC they are applying to requires this.
- **References:** A list of the cited references should be provided to support the content of the protocol.

Informed consent form

An informed consent form is a document used for recruiting potential participants to the research study and obtaining their agreement before they enter it, receive the intervention or have data collected. The form should show study information, and the contact details of the responsible investigators, the ethic committee and of the research institution. It also needs to have space for the name and signature of the researcher (or their representative), the participant and, if necessary, a witness. The procedure of obtaining the informed consent should also comply with international guideline, like the International Ethical Guidelines for Health-related Research Involving Humans (b), while making the informed consent form.

(b) Council for International Organizations of Medical Sciences. International Ethical Guidelines for Health-related Research Involving Humans. Geneva. Switzerland: CIOMS. 2016 https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf (accessed 13 Feb 2021).

Procedures should be in place for non-written consent if, for example, potential participants are visually impaired or illiterate *(1)*; obtaining their consent is likely to require the presence of an independent witness and a note (written, audio or video) indicating the person's willingness to join the study.

Patient information leaflet (if available)

The patient information leaflet is a document providing more detailed information on the study, which would be given to potential participants and those who are recruited to the study.

Any associated study instruments

These include questionnaires, interview guides, focus group discussion guides or other documents related to the research intervention. They may be required to be in English and the native language of the participants. The collection procedure should give an explanation and reason for the data collected, especially if any of this is sensitive data.

Final approval document by the other scientific/technical review committee, or peer reviewers
If the research intervention involves novel technology or instrument, its implementation should have been already reviewed and approved by other relevant peer reviewers or the scientific/technical review committee. The approval document should be provided with the application.

Principal investigator's response to previous review (if the protocol has been submitted before)
If a resubmission is being made to the REC, perhaps following "conditional approval" (which is described below), the researcher should indicate any changes made in the revised protocol in response to the previous review.

Comments made by the other scientific peer review groups (if the protocol has been reviewed by another REC or other committee)
In international studies, approvals from multiple REC may be required. In such cases, any other submissions or approvals should be mentioned, including proof of these.

Information and curriculum vitae (CV) of the researcher(s)
Information, including a curriculum vitae (CV) for each member of the research team may be required by the REC and researchers committee should check the requirements for this with the REC that they will apply to.

Data collection forms, case report forms, patient diaries, and so on (if the study will use these)
Some RECs require these data collection documents to be submitted. The format of each will depend on how the research has been designed, and how the data will be collected and stored.

Recruitment material (if available)
Recruitment material refers to, for example, any advertising tools that will be used to recruit participants to the study. These might be pamphlets, posters or other media. The materials should be compliant with the local culture and language, and should contain sufficient contact information for the researcher and their organization.

7.4.10 Providing potential participants with information on the study

As noted above, the patient information leaflet and informed consent form provide essential background information on the study to potential participants, in lay language. Several components are recommended for both documents. Firstly, they should provide the background and reasons for the study in the target community and explain why the person is being invited to participate. Secondly, they should describe the selection criteria. Thirdly, there should be a clear explanation of the research procedure (including number of visits and estimated research duration), potential safety concerns, rights of participants, data confidentiality, where and how participants can ask questions or raise concerns, procedures and reason for the collection of any sensitive data and the right of the participant to withdraw from the study. Fourthly, contact information of the responsible researcher, the REC and detail of the research institution should be provided.

These documents should include both English and native language versions. In some cases, the native language version might be prepared after ethics approval *(17)* but the REC should usually be provided with the translated document. This is particularly important in international studies that involved populations that speak different languages. Furthermore, if the study will involve multiple distinctive groups, tailored consent might be needed for each of them.

7.4.11 Approval status

After reviewing an application, the REC will usually make a decision that the application is approved, needs modification or is rejected. RECs usually use four classifications to indicate the status of an application after they have processed it (Table 7.4.2).

Table 7.4.2. The description of each different approval responses of ethics application

Status	Description
Approved as submitted	The proposal is approved and no modifications are required.
Approved conditionally; requires amendments or clarifications	The REC requires clarification or amendment about the application, which the researcher is required to provide before it can move forward. The proposal would be re-evaluated after re-submission.
Not approved; requires additional information or rewriting	The REC considered that the proposal was not acceptable but is willing to consider a revision of the protocol if this is submitted in a new application.
Rejected	The REC considered that the proposal was not acceptable and did not advise re-submission.

7.4.12 Responses to questions from the REC

After the research protocol has been submitted, the REC may have comments or questions for the researcher about it. Researchers are typically required to respond to these queries and the requested amendments by preparing a note which includes a point-by-point response to all queries and to submit a revised protocol which shows the changes they have made.

7.4.13 Other communications with the REC

This section describes a variety of situations which need to be reported to the REC, according to WHO *(20)*.

Progress report

For non-cross-sectional studies, a progress report might be required by the REC on an annual basis. This would cover the status of the study, number of participants (recruited, withdrawn and completed), a summary of any major changes to study procedures, serious adverse events,

participants' complaints, and significant updated information or deviation from approved activities which are related to safety or participation.

Application for continuing review (if needed)
If a study needs continuing review, the researchers may need to submit a renewal application including information justifying the renewal and a progress report of the ongoing study, a report from their study's Data and Safety Monitoring Board (if available), and any amended or new documents. Researcher should ensure approval is obtained before the existing approval is expired.

Application for Amendment
If the originally submitted documents and study protocol are amended after approval, the researchers should notify the REC about these amendments. Revised documents include an explanation of the amendment and an amended protocol (highlighting the changes) should be submitted. If the amendment involves significant changes in the study design, additional justification should be provided. The amended protocol should not be implemented before it is approved.

Project closure
When the study is successfully completed or terminates early, the researchers should inform the REC and provide a completed set of documents. This should include the final report with a summary of the study's findings, the latest progress report and any Data and Safety Monitoring Board reports (where applicable), and any other documents required by the REC.

Protocol Deviation
For any protocol deviation has been made during the research (changes of the protocol without the agreement by the sponsor and prior review and documented approval/favourable opinion from the IRB/REC of an appropriate amendment) (ref. a), it should be promptly reported to the REC.

(a). Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2). Swiss. ICH. 2016. https://www.ich.org/fileadmin/Public_Web.../E6/E6_R2__Step_4_2016_1109.pdf

Adverse events
According to *Safety of Medicines: A guide to detecting and reporting adverse drug reactions* published by WHO, an adverse event is any untoward medical occurrence that presents during treatment with medicine, but which does not necessarily have a causal relationship with the treatment *(21)*. In addition to these, some REC also include non-medical occurrences as adverse events. Researchers should check the specific requirements of their REC and ensure that adverse events are reported according to these requirements.

Serious adverse events
A serious adverse event is defined as an untoward medical occurrence which is fatal, life-threatening, requires inpatient hospitalization, results in persisting and significant disability to the subject or causes congenital anomalies or birth defects *(21)*. These should be reported as per REC required. As with adverse events more generally, some REC also include serious nonmedical occurrences as serious adverse events and researchers should check the specific requirements of their REC to ensure that they report serious adverse events appropriately.

7.4

7.4.14 Conclusions

Research ethics applications and approvals are necessary before research involving human subjects, except for those studies that will be limited to publicly available, anonymous data. This chapter provides a general overview of different types of ethics review, procedures, documents required and other important points, which are part of the WHO guidelines for ethics approval. However, the variety of national and institutional policies around ethical approval mean that there is no single, globally-agreed standard or requirement that applies to all research ethics systems or RECs *(14)*. Researchers should therefore always check the specific requirements of the REC they are applying to before submitting their application.

7.4.15 Key messages

- **All research studies involving human participants should be reviewed and approved by research ethics committee. It is the committee's decision whether a study should be exempted from the full reviewed process.**
- **Research should be conducted in ways that protect the safety and confidentiality of the participants, both physically and mentally (in protocol and document) and be carried out in accordance with the principles underpinning the Declaration of Helsinki.**
- **The type of ethics review required will depend on the nature and the urgency of the study.**
- **Current ethics review procedures might not be fully applicable to the challenges encountered in the Health EDRM context, especially during rapid onset emergencies and disasters because of the relatively long lead time of non-emergency ethics review processes. Changes in the ethics review procedure are needed to accommodate the special needs for emergency researches.**
- **Ethics application requirements vary across REC. Researchers should check the requirements of the REC they plan to submit their application to.**

7.4.16 Further reading

Council for International Organizations of Medical Sciences and WHO. International ethical guidelines for biomedical research involving human subjects. Geneva, Switzerland: CIOMS. 2002 https://cioms.ch/shop/product/international-ethical-guidelines-for-biomedical-research-involving-human-subjects-2 (accessed 10 January 2020).

Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2). Swiss. ICH. 2016. https://www.ich.org/fileadmin/Public_Web.../E6/E6_R2__Step_4_2016_1109.pdf Kayano R, Chan EY, Murray V, Abrahams J, Barber SL. WHO Thematic Platform for Health Emergency and Disaster Risk Management Research Network (TPRN): Report of the Kobe Expert Meeting. International Journal of Environmental Research and Public Health. 2019: 16(7): 1232.

Panel on research ethics. The Tri-Council Policy Statement 2: Course on Research Ethics. Ottawa, Canada: Government of Canada. [Online tutorial] https://tcps2core.ca/welcome (accessed 10 January 2020).

Policy on research involving human participants. London, United Kingdom: Wellcome Trust https://wellcome.ac.uk/funding/guidance/wellcome-trust-policy-position-research-involving-human-participants (accessed 10 January 2020).

World Medical Association Declaration of Helsinki - Ethical principles for medical research involving human subjects. Ferney-Voltaire, France: World Medical Association. 2013 https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects (accessed 10 January 2020).