



**World Health
Organization**

Patient Safety

A World Alliance for Safer Health Care

WHO Patient Safety Small Research Grants

A Resource for Applicants



Better Knowledge for Safer Care

Introduction

This resource is intended to help applicants prepare their proposal for funding as part of WHO Patient Safety Small Research Grants. It provides information on the aims and objectives of the initiative, access and eligibility criteria, application and assessment processes, ethics requirements and provision of funding, as well as the reporting and administration of grants.

The information is organized into three parts. Part one contains general information on the small grants initiative. Part two provides specific information on how to complete the application form. Part three explains the application assessment and selection process. Please read this resource in full before completing the application.

You can visit the patient safety website for further information:
www.who.int/patientsafety/research/grants/en

The final date for the 2009 small research grants submissions is 30 September 2009.

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Part 1: Overview

1.1 About WHO Patient Safety - A World Alliance for Safer Health Care

WHO Patient Safety was launched in October 2004 by the Director-General of WHO. It aims to increase awareness and political commitment to improve patient safety, including policy and practice, in all WHO Member States. Research for Patient Safety is one of the key action areas. The Research Programme aims to foster patient safety research worldwide and to spread and use research findings and evidence to improve patient care globally.

1.2 About the WHO Patient Safety Small Research Grants

The Small Research Grants aim to stimulate research in patient safety by providing seed funding for small well-defined, well-designed research projects, which focus on priority areas and can be achieved within 12-18 months. It is expected that this initiative will also contribute to building local research capacity and will help raise awareness about patient safety at both local and country levels. Specific objectives include:

- to increase research on patient safety by providing seed funding for 20–30 small research projects each year;
- to contribute to building local capacity for research on patient safety by providing grants to research institutions and research teams in developing countries and countries with economies in transition, especially to projects in which young researchers and those in early or mid-career are the lead investigators; and
- to promote the culture of patient safety by improving dissemination of research findings.

1.3 Funding available

This year, up to US\$ 500 000 has been allocated to fund 20–30 grants for projects to start in 2010. Funding will range from US\$ 10 000 to US\$ 25 000 per grant. The amount is flexible, but the grant must be appropriately justified. The grant may be renewable if the first project is completed satisfactorily and if funding is available. The grant will support the direct costs of research (see Conditions of Grants for more details) and is to be used within 12-18 months following the transfer of the first instalment. The project should commence within two months of the date specified in the Letter of Contract. In exceptional circumstances, an extension of the project and use of funds may be granted, subject to written approval from the WHO Patient Safety.

1.4 Eligibility

Institution: Funding will be provided through an administering institution (host institution) which will be the fund holder and legal entity for contractual purposes. This ideally should be

the main affiliated institution of the principal investigator. Other co-investigators must also provide details of their affiliated institutions. Eligible institutions include universities or other research and academic centres, hospitals, community based organizations, non-governmental organizations, government departments and collaborating centres, for example. In all cases, the host institution will show proof of sufficient research capacity and of experience in managing and conducting research projects.

Researchers: Researchers at all stages of their careers are eligible to apply, although submissions from mid-career researchers or those aged 45 years or younger are especially encouraged.

Principal investigator: The principal investigator must be affiliated to a recognized institution in the country in which the research project will be conducted. He or she needs to demonstrate the ability to lead and complete a research project with similar characteristics to the project submitted. In the case of a multinational research project, the study will be encouraged to submit one or more investigators from each country.

Country: The focus of this programme is primarily researchers from developing countries or countries with economies in transition. Researchers from developed countries can, however, be co-investigators or collaborators. Researchers from developed countries are eligible to apply as principal investigators, but priority will be given to applications from developing countries and countries with economies in transition.

Collaboration: Collaborative research projects will be particularly encouraged. These may include collaboration between institutions in the same country, between countries within the same region or between developing/transitional countries and developed countries. Special consideration will be given to applications that combine the efforts of researchers and clinicians, health care professionals or policy-makers who are actively involved in the project.

1.5 Conditions of grant

The grant is to support the research project described in the application. It is cash-limited at the value stated in the contract. There is no scope for increasing the level of grant awarded. The fund is intended to contribute to the operational costs and not to substitute the salaries of the investigators. The expenditure must conform to the budget items outlined in the approved proposal.

The grants will be administered through the Technical Service Agreement. Conditions of Grants provides details of the terms and conditions of the grant. Reports on expenditure (Financial reports) will be required at mid term and at the end of the project. The forms for these reports will be made available on the WHO Patient Safety website.

1.6 Institutional approval

Applicants should be aware that evidence of approval and endorsement by the host institution will be required for proposals that are selected for consideration. However, it is not required at the time of submitting an application. The principal investigator will be contacted and asked for evidence of institutional support when their proposal has been selected for further consideration. For applications selected for funding, the contractual arrangement will be negotiated between WHO and the host institution.

1.7 Project management

All applications must demonstrate a competent team and a sound project management structure which are sufficient to successfully implement the project. The principal investigator should provide information on members of the project team and their specific roles in the project.

If selected for funding, each principal investigator and the corresponding project manager will be expected to work collaboratively with the designated technical officer (TO) of WHO Patient Safety Small Research Grants in order to monitor and evaluate the project.

1.8 Confidentiality

Unless otherwise indicated, information contained in the applications is regarded as confidential and will be treated as such according to WHO requirements. Information comprising the names of successful grant applicants, their administering and/or collaborating institutions, the title of the research project and the funding awarded may be published on the WHO Patient Safety website and/or in the annual report.

1.9 Ethics clearance

WHO Patient Safety requires the research it funds to be conducted in an ethical manner, which respects the rights of research participants and recognizes the responsibilities of the researchers. The principal investigators and the host institution are responsible for ensuring that ethical issues relating to the research project, if any, are identified and brought to the attention of WHO Patient Safety.

1.9.1 National Ethics Review Body

All research projects funded under this initiative must conform to the ethical requirements set out by the relevant /appropriate national ethical review body. Evidence of ethics approval will be required if your proposal is selected for further consideration. It is not required at the time of submitting the grant application. We raise the issues now

so that you are aware of it and take it into consideration when designing your study.

1.9.2 WHO Research Ethics Review Committee (ERC)

Research projects funded through this initiative are subject to approval from the WHO Research Ethics Review Committee (ERC). The Small Research Grants Manager will collate all research project protocols and coordinate the submission to the ERC.

Please ensure that your proposed project conforms to the requirements of the ERC. For your information, the WHO ERC has provided a range of resources which can be found at http://www.who.int/rpc/research_ethics/en/.

Please consult these resources when preparing your application:

- Guide for writing a Research Protocol (http://www.who.int/rpc/research_ethics/guide_rp/en/index.html)
- A practical guide for health researchers (http://www.emro.who.int/publications/pdf/healthresearchers_guide.pdf)
- Guidance documents on seeking informed consent (http://www.who.int/rpc/research_ethics/Process_seeking_IF_printing.pdf)
- Examples of informed consent form (http://www.who.int/rpc/research_ethics/informed_consent/en/)
- Checklist for Principal Investigator (http://www.who.int/entity/rpc/research_ethics/Checklist_for_PI.dot)

1.10 Lodging an application and further information

The due date for submission is 30 September 2009. Applications submitted after the due date will not be considered. Only online submissions are accepted. Each application will be required to submit the following:

1. A registration form. This is an online form and must be completed via internet.
2. Application Form Part 1. This contains information about the investigators and must be uploaded as an attachment.
3. Application Form Part 2. This is the study proposal which must be uploaded as an attachment
4. Study tools. This is an option. Applicants can choose to incorporate study tools into the Application Form Part 2 or submit the study tools separately to ensure that the files do not exceed the size limit (5MB).

For each application, only three attachments are allowed. Thus, the principal investigator must ensure that all application forms are completed and appropriately formatted before attempting the online submission.

Part 2: Completing an Application

2.1 Application Form

All applications are required to use the provided form and to provide all relevant information. **Applications that do not conform to these requirements will not be considered.** The application must be written in English.

There are two application forms - Part 1 and Part 2. The Application Form Part 1 collects information required for administrative purpose and information about researchers and their institutions. The curriculum vitae of the investigators and any information about the institutions, networks or collaborations must be enclosed to this form as appendices.

Application Form Part Two concerns the research proposal only. Do not include any information that may identify investigators and/or their affiliated institutions (except the file name). Any information relevant to the proposal, such as informed consent form and study tools should be included in this form as appendices. Study tools may be submitted separately, if needed, to ensure that the file does not exceed the size limit (5MB).

More detailed instructions for each section of the proposal are available in the application forms.

All applications are required to adhere to the following:

- Each application can upload up to three (3) files, including Application Form Part 1, Application Form Part 2 and Study tools;
- Application files may be in Word or PDF format;
- Use the principal investigator's name as a file name with appropriate suffix. (e.g. Small_Grant_app1, Small_Grant_app2, Small_Grant_tools);
- Use either of the following fonts: Arial (10) or Times New Roman (11 or 12);
- With the exception of title or headings, use sentence case for the body texts of the application and the proposal. Do not use ALL CAP. Do not use bold font;
- Format the application and proposal appropriately. There should not be blank pages or gaps between paragraphs;
- Start each new section with a new page;
- The CV of each investigator must not exceed 4 pages;
- The document should be spellchecked and adjusted for any blank or extra spaces between words.

The information in the application form is organized into two parts. Part one contains information about investigators and their affiliated institution as well as information about the project team. This section will be detached before distributing the applications to the expert reviewers. Part two contains detailed information on the research proposal, which will be assessed for the scientific merit and policy relevance of the proposed project.

2.1.1 Part I: Administrative information

This section includes details of applicants i.e. principal investigators and co-investigators, administering institution and collaborating institutions. Please fill in all fields in this section. If the questions or items are not applicable, indicate "Not applicable".

The project team should comprise an appropriate mixture of skills and distribution of roles and responsibilities. The details of the composition of the project are important as the reviewers will assess whether the applicants have sufficient and appropriate skills and resources to complete the project.

List all the relevant people who will be part of the project team, their current positions, their affiliate organizations and their specific roles in the project. For key project staff such as principal investigators, co-investigators, project manager, please provide a summary of their curriculum vitae (not more than 4 pages).

2.1.2 Part II: Research proposal

This section entails the study rationale and objectives, design, methods, data analysis and management plan, expected outcomes and results dissemination. You must fill in all the fields. Where the questions are not relevant, indicate "Not applicable". Make sure you provide precise and concise information. Care should be taken in completing this section as the information will determine the scientific merit of the proposal. It is important to provide sufficiently detailed information on the project plan and timeline.

Your budget should be as realistic as possible and within the limit of the grant amount. As much as appropriate, make sure you provide information on budget items and provide justification adequately. You may provide references to other projects of similar size and design.

Part 3: Application Assessment and Selection

3.1 Research priority areas

Only research projects pertinent to patient safety issues will be considered. Research on efficacy of drugs or medical devices are not in the scope of this grants programme.

The programme focuses on applied research. Applications that attempt to identify local solutions, or evaluate the effectiveness and cost-effectiveness of existing solutions are especially welcomed.

The grants will target research proposals that correspond to the global research priorities of WHO Patient Safety, of which the details are available at:

<http://www.bmj.com/cgi/content/full/bmj.b1775>.

The current call for proposals will focus on the topics listed below, although studies on other topics among the global research priorities may be considered

- Counterfeit and substandard drugs;
- Maternal and newborn care;
- Safe injection practices;
- Improving competencies, training and skills;
- Communication and coordination across care pathways;
- Latent organizational failures.

3.2 Peer Review Process

WHO Patient Safety Small Research Grants are awarded on a competitive basis. Applications will be evaluated via a peer review process to ensure a fair, equitable, and transparent assessment of their scientific and technical merit. The Research Programme of WHO Patient Safety oversees, coordinates and manages the peer review process.

There are three steps in the process:

1. The screening panel will conduct an initial review of grant applications to ensure the eligibility, completeness and accuracy of the information provided and the fitness of the proposal to the research priorities. Only proposals that pass the screening process will be peer-reviewed. An identification number (ID) will be assigned to each application to ensure confidentiality and anonymity. The identity of the researchers and their affiliated organizations will be detached from the proposal.
2. This is a peer-review assessment, which will be conducted independently by an expert panel. Members of the review panel comprise experts in varying disciplines from different countries around the world covering all WHO regions. The review will be conducted in two phases.

Phase one involves the assessment of the scientific merit, project management capacity and policy relevance of the proposed study. Applications will be assessed according to the review guidelines using pre-determined criteria, which are available on the website. Each criterion consists of a number of questions to which the reviewers are asked to assign a score from 1 to 4, where 4 represents the most valuable. In addition, the reviewers are also asked to provide comments on specific aspects of the proposal.

The applications will then be ranked and considered based on the total summed scores and the reviewers' comments. Proposals that are not recommended for funding or those that require major modifications will not be given further consideration. Only proposals with high average scores and with positive recommendations from the reviewers will be selected for "Phase two" assessment.

Phase two involves an assessment of the capacity and ability of the principal investigators, the research team and the institutional facilities. Researchers must demonstrate that they have the necessary skills, experience, resources and institutional support to carry out and complete the project and deliver the outcomes as outlined in the proposal. At this stage, the identity of the researchers and their affiliated institutions will be provided to the reviewers to facilitate their assessment of the applications. The applications will be ranked again based on the newly obtained scores. The outcomes of this process will inform the final selection, which will be deliberated by the Selection Panel.

3. The final step in the assessment process is ethical clearance by the WHO Ethics Review Committee. Proposals selected for consideration will be further developed into full study protocol prior to submission to the WHO ERC for final ethical clearance. The PIs will be expected to work closely with the Small Grants team on this process. Only applications that receive approval from the WHO ERC will be recommended for funding.

3.3 Review Criteria

The grant selection review criteria include the scientific merits of the study, and project management and organizational capacity.

Scientific merits of the study:

- Relevance of the research questions;
- The appropriateness and robustness of the study design in relation to the study questions;
- Significance and originality;
- Internal validity, methods and data;
- Policy relevance.

Project management and organization:

- Researchers qualifications and experience;
- Project management plans;
- Facilities, resources, and environment;
- Ethical consideration;
- Adequacy of the budget and value for money.

3.3.1 Scientific merits of the study

Relevance of the research questions

This is to assess whether the research questions correspond or have relevance to the research priorities identified by WHO Patient Safety. For research questions linked to local priorities, you must demonstrate that the proposed questions are considered priorities by national authorities. The reviewers will also assess the likelihood that the results of the study would be relevant for policy, organizational or managerial purposes, or clinical or patients' purposes. Please ensure that your proposal clearly states the research questions and the study objectives.

Significance and originality

This is to assess the contribution of the proposed project to knowledge and practice relating to patient safety. The reviewers will evaluate whether the proposed study addresses an important problem, contributes to the advancement of treatments and interventions for patient safety, or contributes to clinical practice and health-care services. The reviewers will also evaluate the potential contribution of the study to research methods and scientific knowledge. Ensure that your proposal demonstrates originality or innovation in terms of the adequacy of the literature review, the sufficiency of the rationale and the importance and significance of the expected outcomes.

Internal validity, methods and data

This is to assess whether the conceptual framework, design, methods and data analyses are adequately developed, well-integrated and appropriate to respond to the research questions. The reviewers will assess whether the key concepts and variables are clearly defined, the study population and the sample size are appropriate, adequate and justified, whether the analytical plan is adequate and corresponds to the research question, and whether the applicant acknowledges potential problems and considers alternative tactics or ways to minimize them. The information provided in this section will be essential for "Phase one" peer review assessment. Please ensure that your application contains sufficient, but concise and precise information.

Policy Relevance

The reviewers will also assess the potential contributions of the proposed study to the development of practical or innovative policy or guidelines for improving patient safety.

3.3.2 Project management and organization

Investigators

This section will consider whether the principal investigators are qualified and sufficiently skilled and experienced to carry out the project, whether the composition of the project team is suitable in terms of mixture of skills, delineated roles, responsibilities etc., and whether the investigators are knowledgeable about the subject area.

Project management

The project management section looks at the plans for organizing and carrying out the project in a satisfactory manner. Whether the management plans, timeline of the project, the flow of the project in terms of key events and products, and the personnel's time and resources are sufficiently allocated; whether the roles, responsibilities and skills of the project team are well defined, and also whether the plans for dissemination of results and data sharing are well-described and reasonable.

Facilities, resources, and environment

Some of the key questions here are: Are the resources of the administering institution and other study sites adequate? Has the application been endorsed by a relevant authority? Please enclose appropriate documentation of agreements among participants and collaborating organizations, if applicable. Please also enclose a letter from hosting organization as evidence of institutional support. Do the scientific environment or subject populations have unique features which will benefit the project, or employ useful collaborative arrangements?

Ethical consideration

It is essential that the proposal addresses potential ethical issues. Where the study includes human subjects either directly or indirectly, the proposal will need to adequately describe the risks to and approaches for protecting subjects. In these cases, the proposal needs to include an appropriate informed consent. All applications are expected to satisfy the requirements of the relevant local ethics body and to adhere to any relevant legislation of the country of the host institution.

3.3.3 Budget

Applicants are advised to ensure that the proposed budget is reasonable and appropriate for the proposed project. The reviewers will look for good value for money. You should plan your budget realistically, itemise it clearly and sufficiently justify it. WHO may propose alternative budgets for successful grant applications.

3.4 Review by the WHO Ethics Review Committee

The purpose of this process is to ensure that the proposed projects conform to WHO ethical requirements and will be conducted in an ethically appropriate manner. Only applications that are approved by the WHO Ethics Review Committee will be considered for funding. Thus, you are advised to carefully consult with WHO Ethics Review Committee requirements when preparing the proposal.

3.5 Review Process and Conflict of Interest

The assessment of the application is carried out independently and anonymously by each reviewer. The Research Programme will remove any information that may identify the study authors and/or corresponding institutions from the grant proposals prior to distributing them to the reviewers. This is an attempt to minimize the bias and conflict of interests among members of the review panel.

If however, the reviewers are or are becoming aware of the identity of the authors and/or of hosting institutions, they must contact the Research Programme and declare any possible conflict of interest or excuse themselves from reviewing that particular proposal.

Membership of the review panel does not disqualify people from applying for a grant provided that their applications meet the grant eligibility criteria. If they do so, however, they must contact the Research Secretariat and disclose the details of the projects in which they are involved and their own role within the project. They must not reveal the details of their applications to other members of the review panel to avoid any possibility of bias.

3.6 Unsuccessful Applications

WHO will communicate the outcome of the selection process related to all applications. Unsuccessful applications may be resubmitted to consecutive calls for proposals.

Applicants who disagree with the recommendations of the review panel may write to the Research Programme within three weeks of receiving the letter of resolution by WHO requesting additional review. Provided the arguments of the principal investigator are solid enough to respond to the queries of the review panel, the Research Programme will seek an additional independent review. No new nor amended research proposals will be accepted for this additional independent review.

3.7 Indicative Timeline for resolution of applications

Activity	Date
Call for proposals	1 July 2009
Closing date for applications	30 September 2009
Peer review of proposals	October - November 2009
Communication of the review outcomes	December 2009
Protocol preparation	January - February 2010
Applications reviewed by the WHO Ethics Review Committee	March - April 2010
Research projects commence	April - May 2010
Mid-term report due (six months after project commencement)	November 2010
Final report due (two months after project completion)	July - December 2011

3.8 Checklist

To facilitate speedy review, before submitting your application ensure that you have completed all sections, answered the questions and provided all the required comments. The key items are summarized in the table below. A complete check list (as suggested by the WHO ERC) is available at http://www.who.int/entity/rpc/research_ethics/Checklist_for_PI.dot.

Key Items	Y/N?
Have all questions been answered and all sections completed? Are all of your responses correct?	
Are the details of your institution correct?	
Have you provided sufficient information to demonstrate that the selection criteria have been addressed?	
Have you provided sufficient information on budget items?	
Is the budget reasonable for your proposed project and has it been justified?	
Have you attached the required documents?	
Have all the necessary signatures been obtained?	